



US009204990B1

(12) **United States Patent**
Berven

(10) **Patent No.:** **US 9,204,990 B1**
(45) **Date of Patent:** **Dec. 8, 2015**

(54) **WATERPROOF COVER FOR OSTOMY BAG AND METHOD**

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 192 days.

(21) Appl. No.: **13/729,009**

(22) Filed: **Dec. 27, 2012**

Related U.S. Application Data

(63) Continuation-in-part of application No. 13/018,210, filed on Jan. 31, 2011, now Pat. No. 8,377,020.

(60) Provisional application No. 61/434,348, filed on Jan. 19, 2011.

(51) **Int. Cl.**
A61F 5/44 (2006.01)
A61F 5/443 (2006.01)

(52) **U.S. Cl.**
CPC **A61F 5/443** (2013.01)

(58) **Field of Classification Search**
CPC A61F 5/44; A61F 5/45; A61F 6/08; A61F 13/20; A61F 13/26; A61F 13/34; A61F 13/49; A61L 24/00; A61L 24/04; A61L 24/06; A61L 28/00; A61M 27/00
See application file for complete search history.

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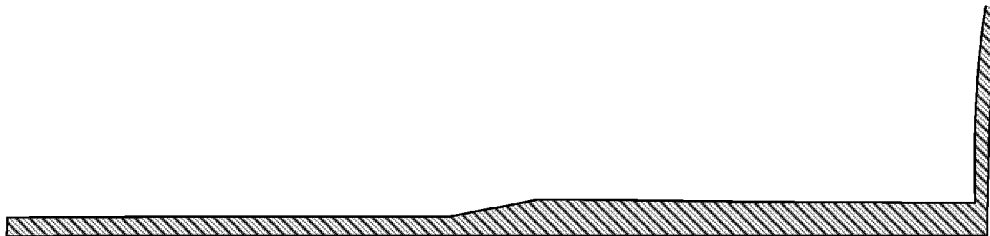
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(57) **ABSTRACT**

The present invention is an ostomy-bag cover that provides a waterproof covering for an ostomy bag. This permits a patient wearing an ostomy bag to shower or bathe without getting his or her ostomy bag wet. In some embodiments, the ostomy-bag cover is constructed such that the patient can engage in water related activities, including swimming, while wearing the ostomy-bag cover over the ostomy bag and prevent the ostomy bag from getting wet. In some embodiments, the ostomy-bag cover includes a resealable opening configured to allow the patient to empty the ostomy bag without the need to remove the ostomy-bag cover. In other embodiments, the ostomy-bag cover includes a waterproof exhaust vent to allow air to be removed from the ostomy-bag cover.

20 Claims, 27 Drawing Sheets



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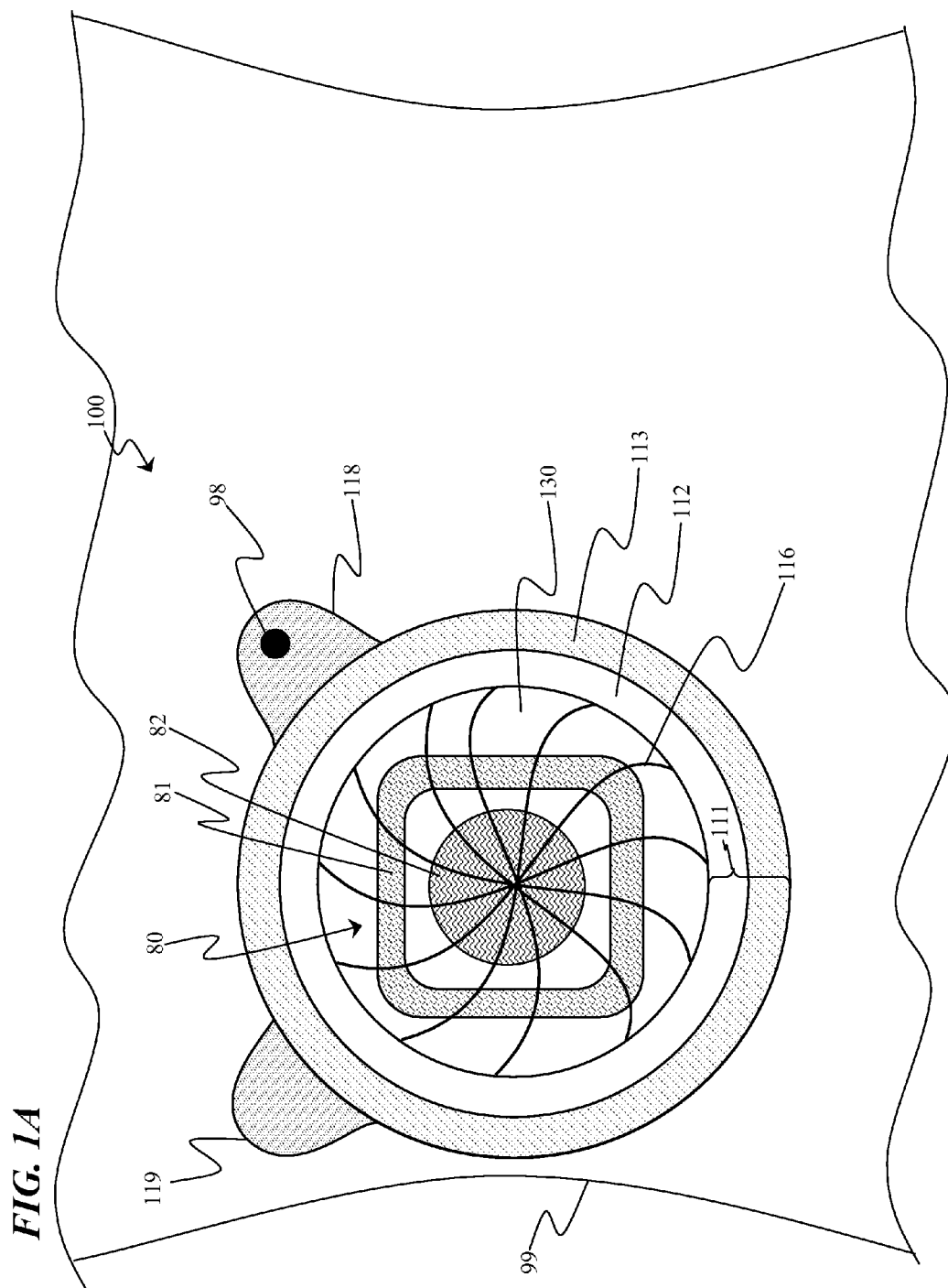
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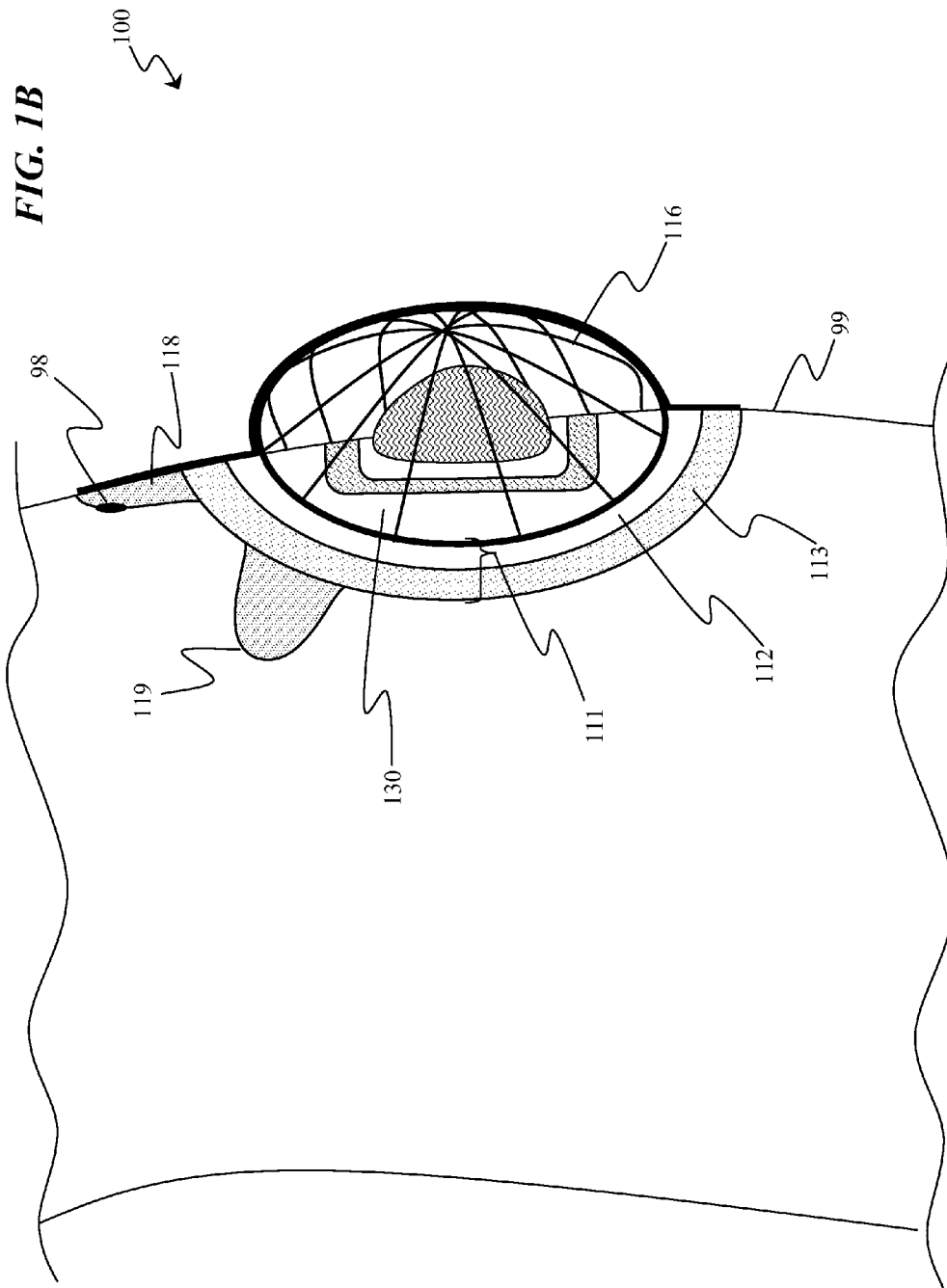
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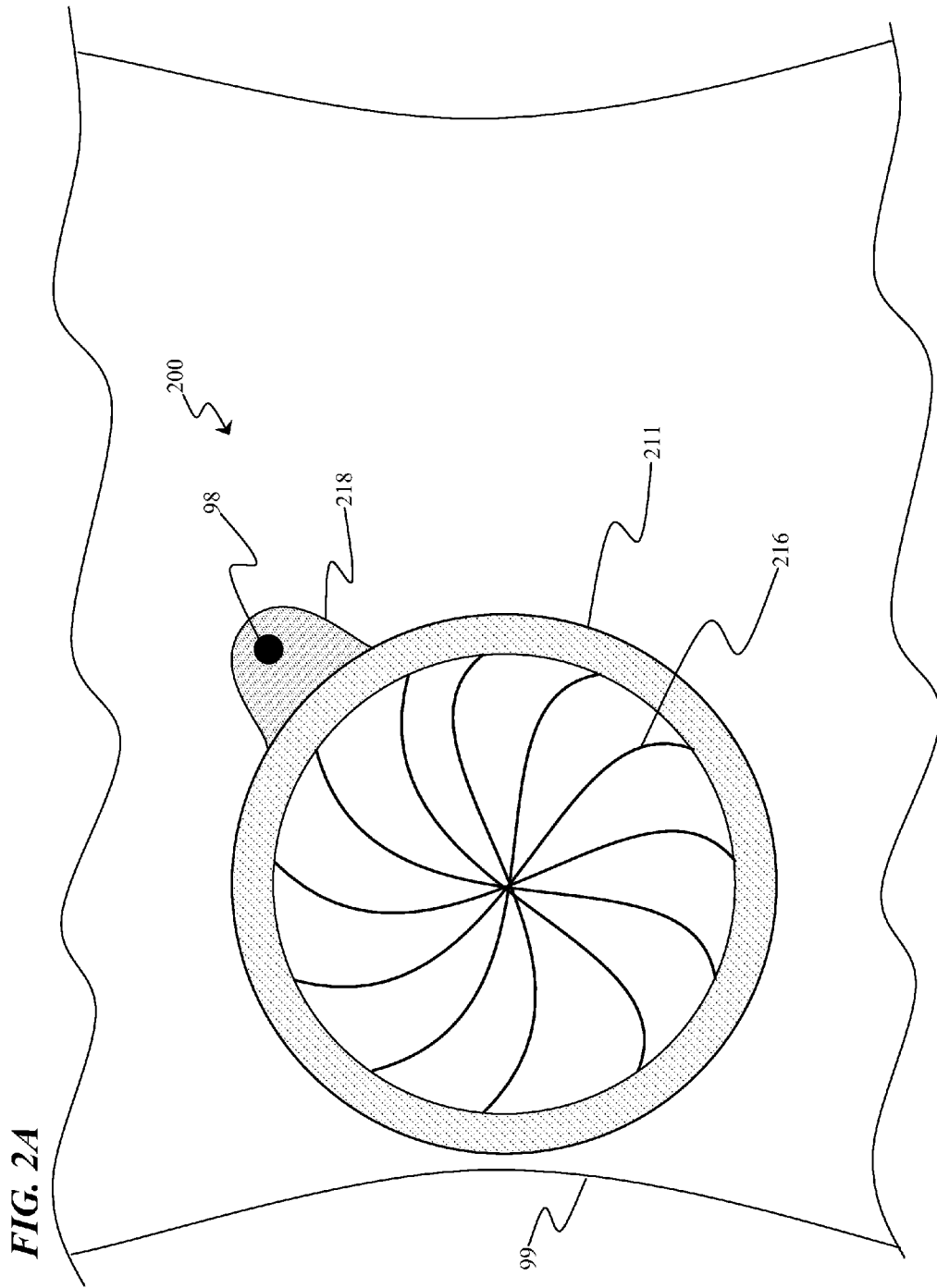
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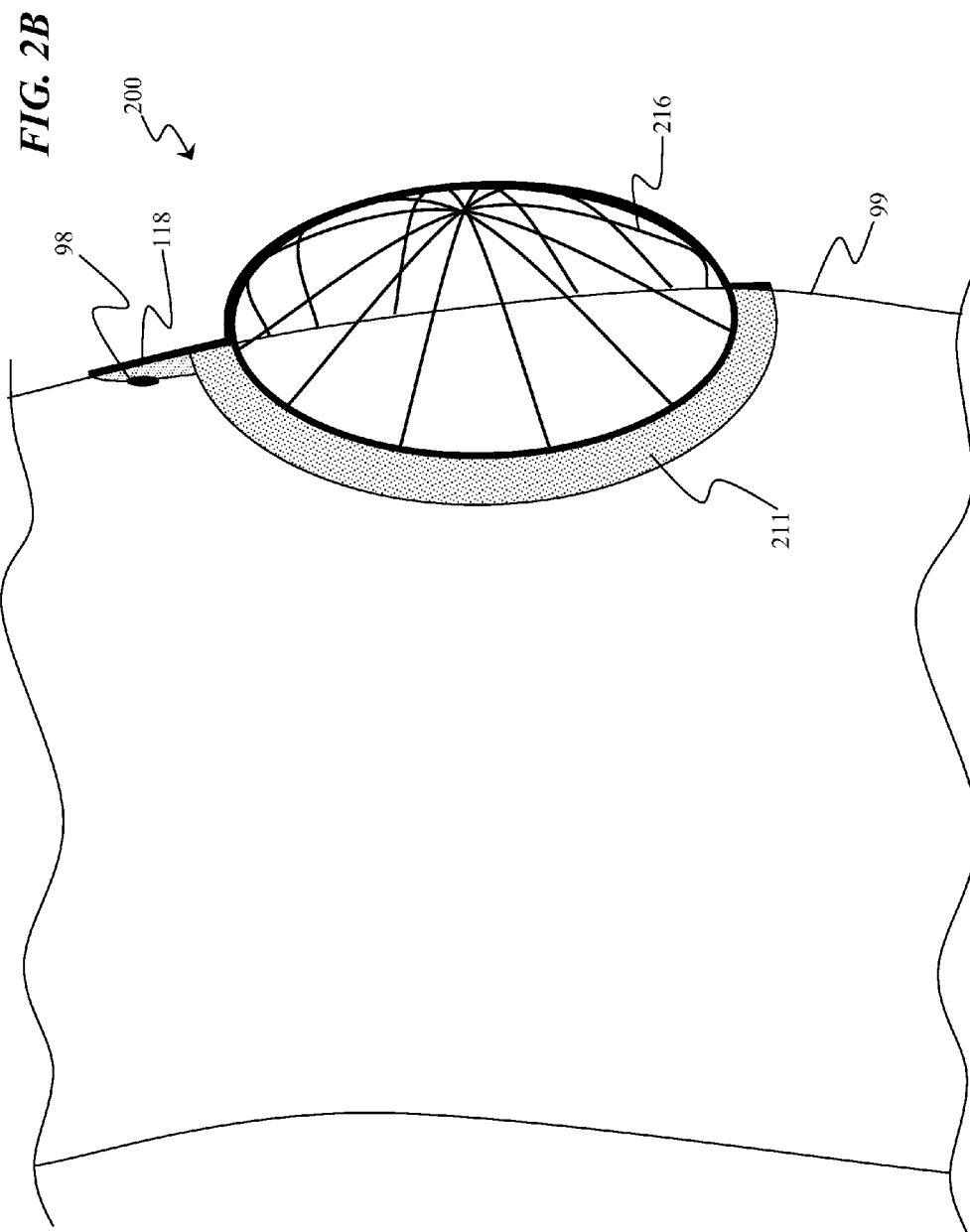
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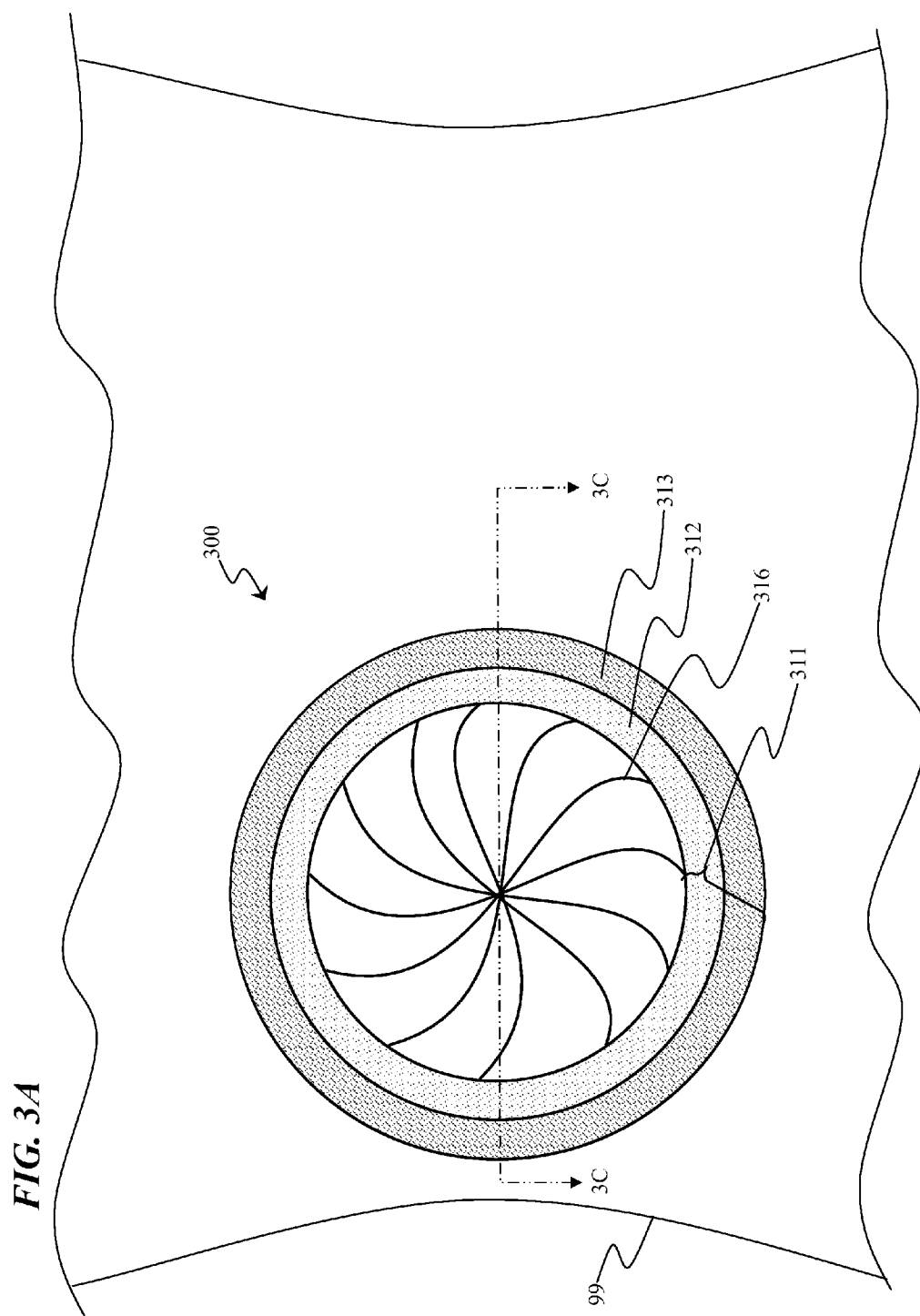
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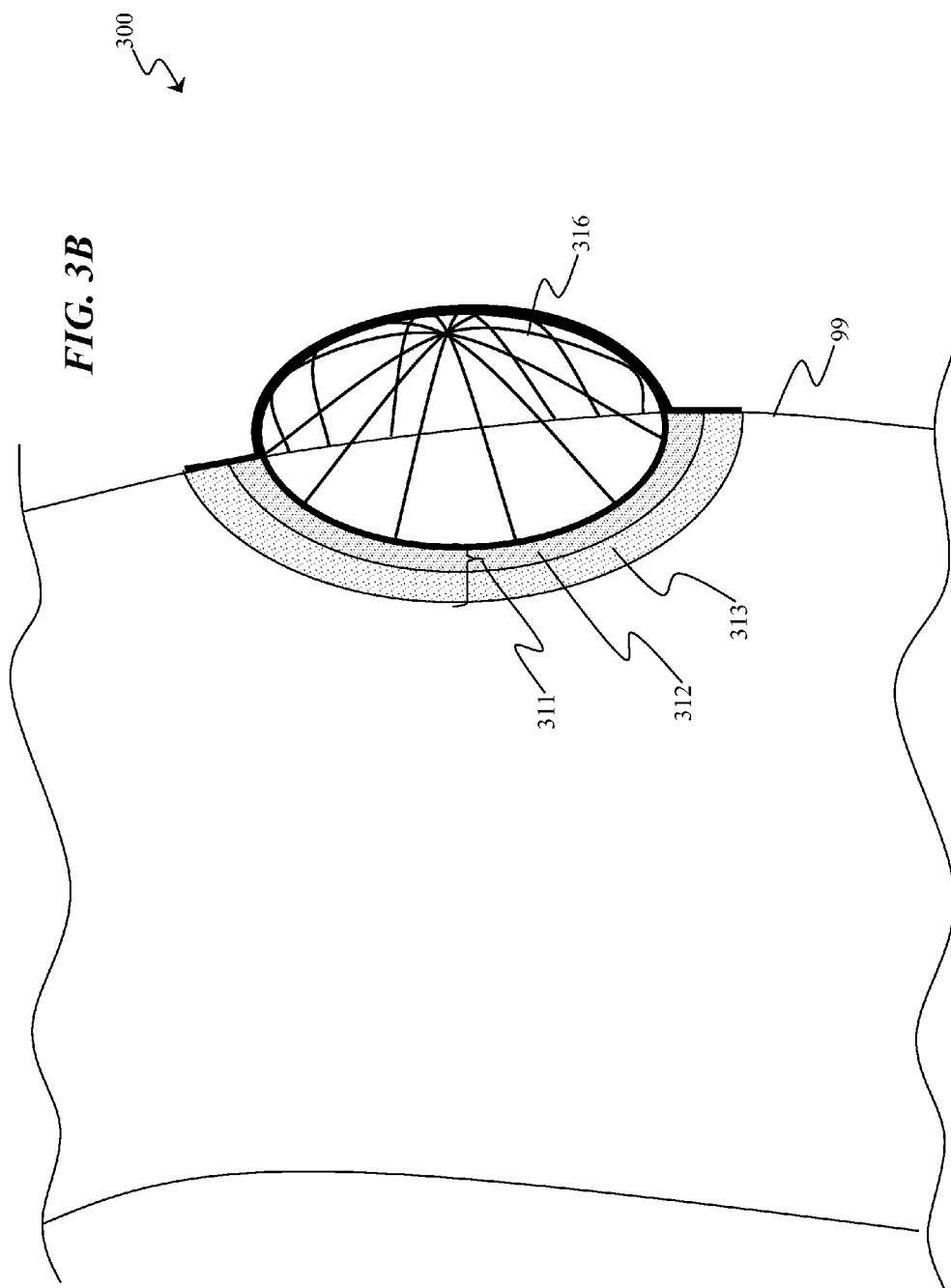












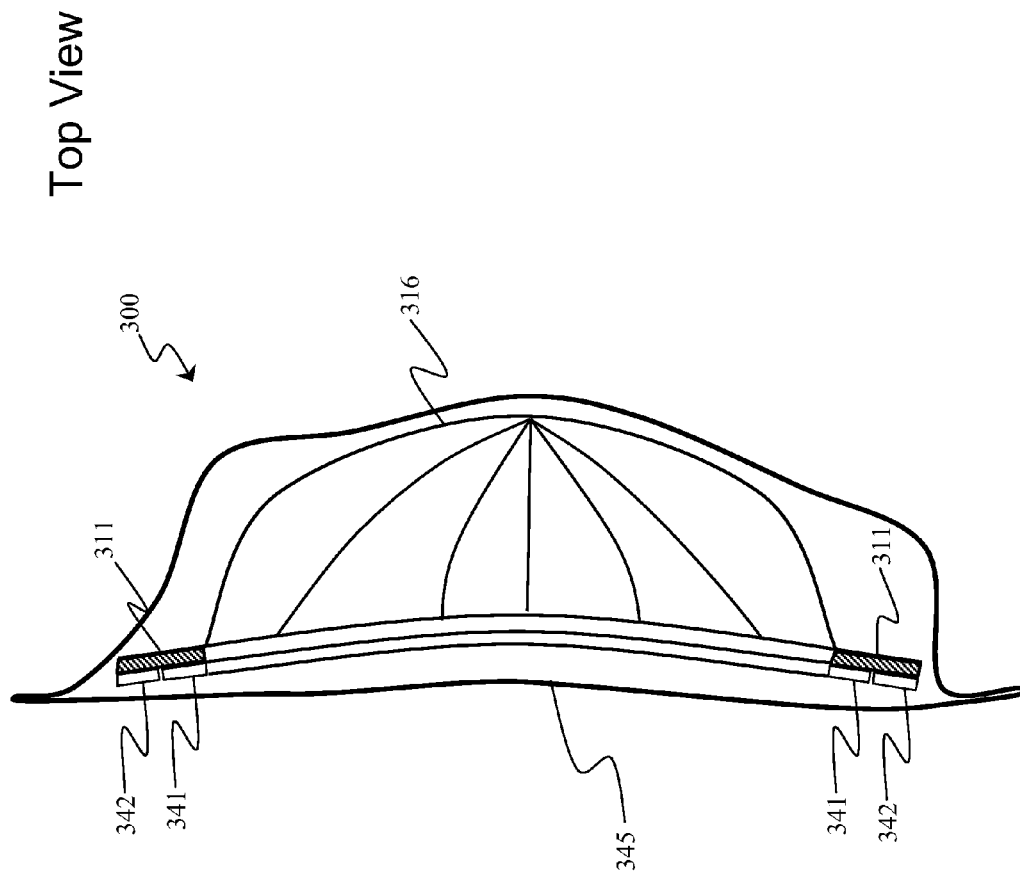
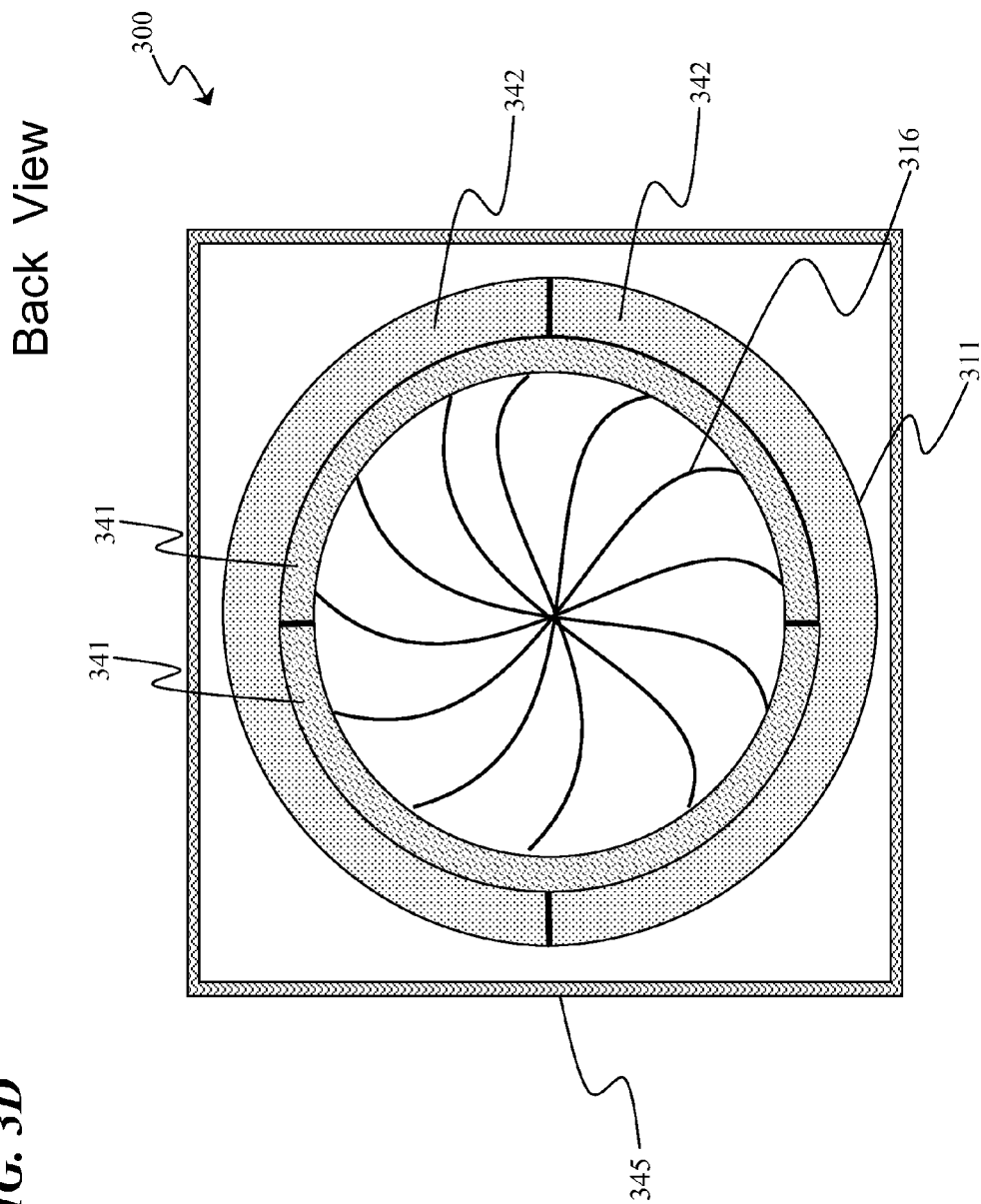


FIG. 3C

FIG. 3D



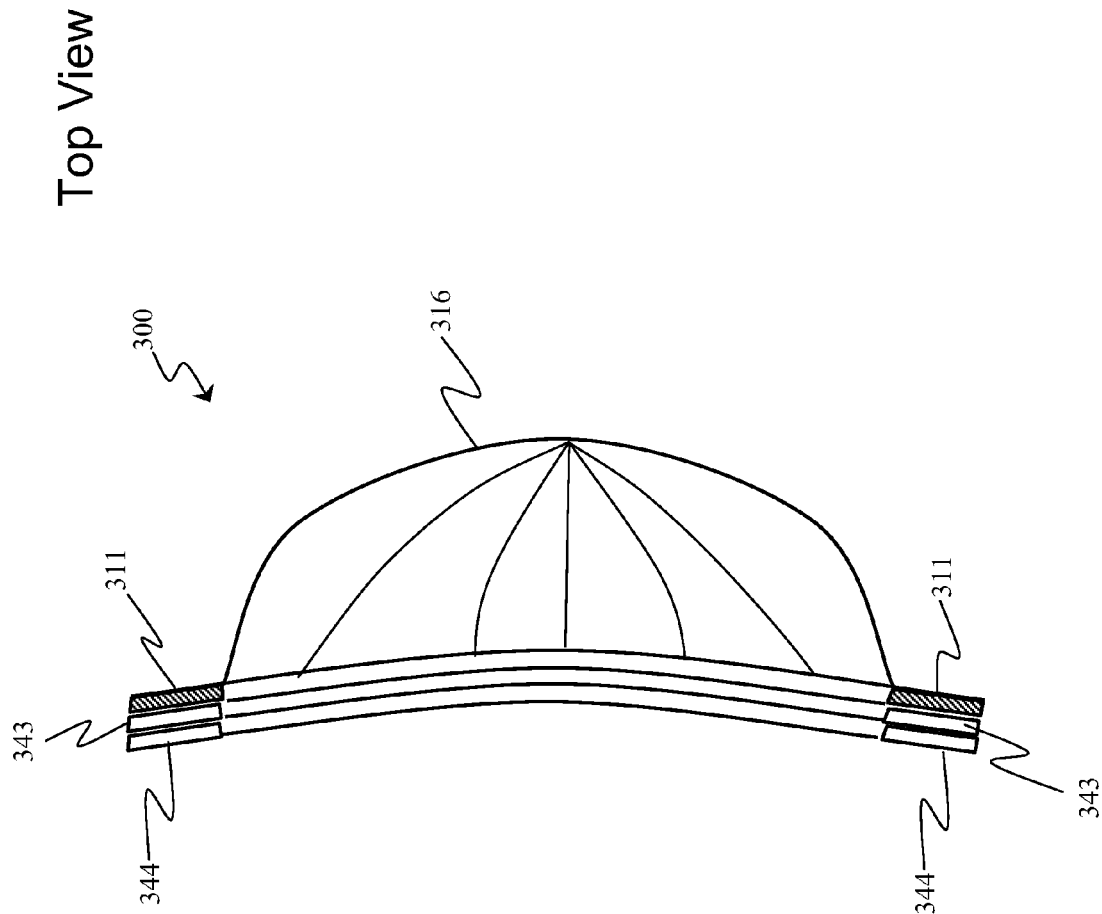
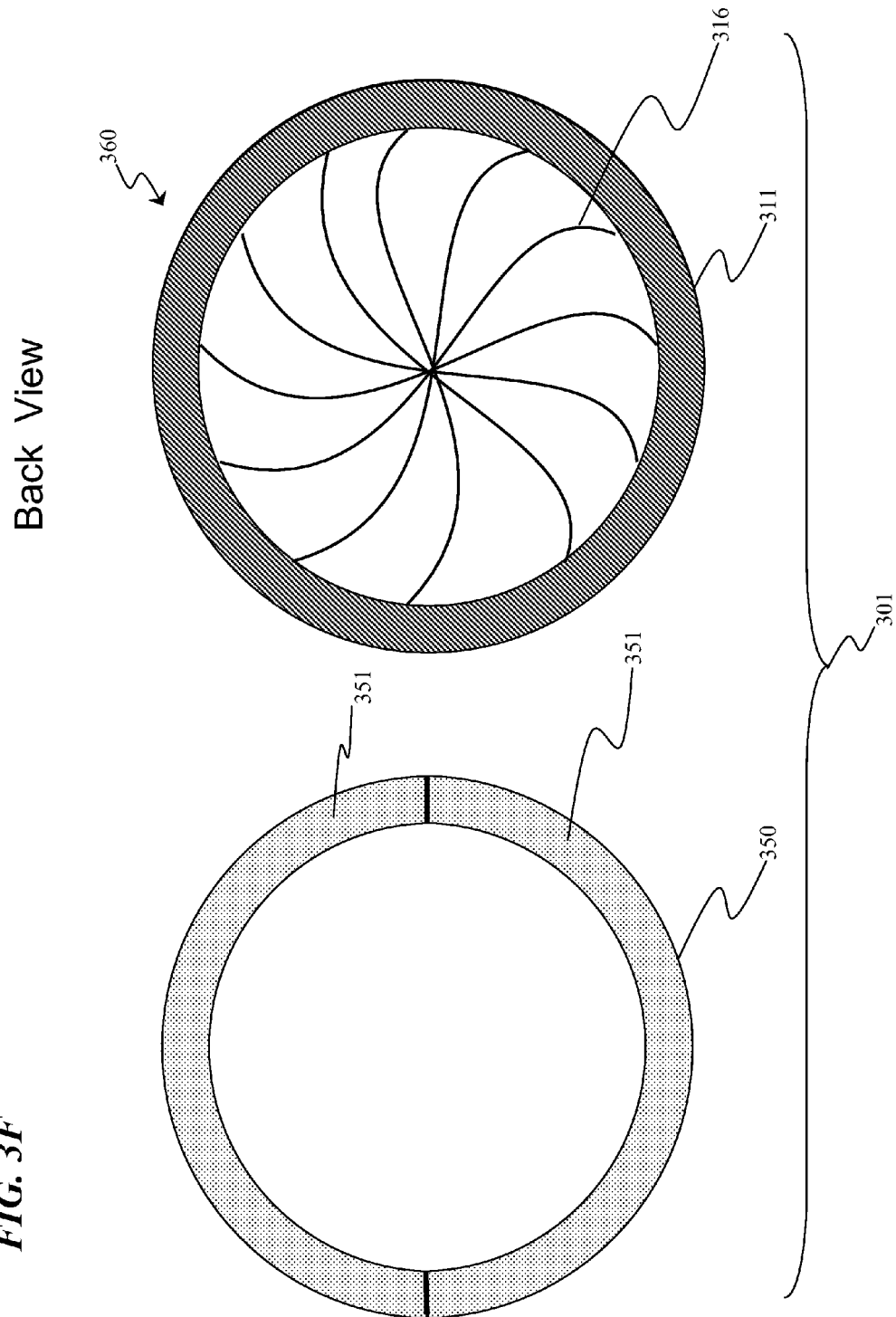
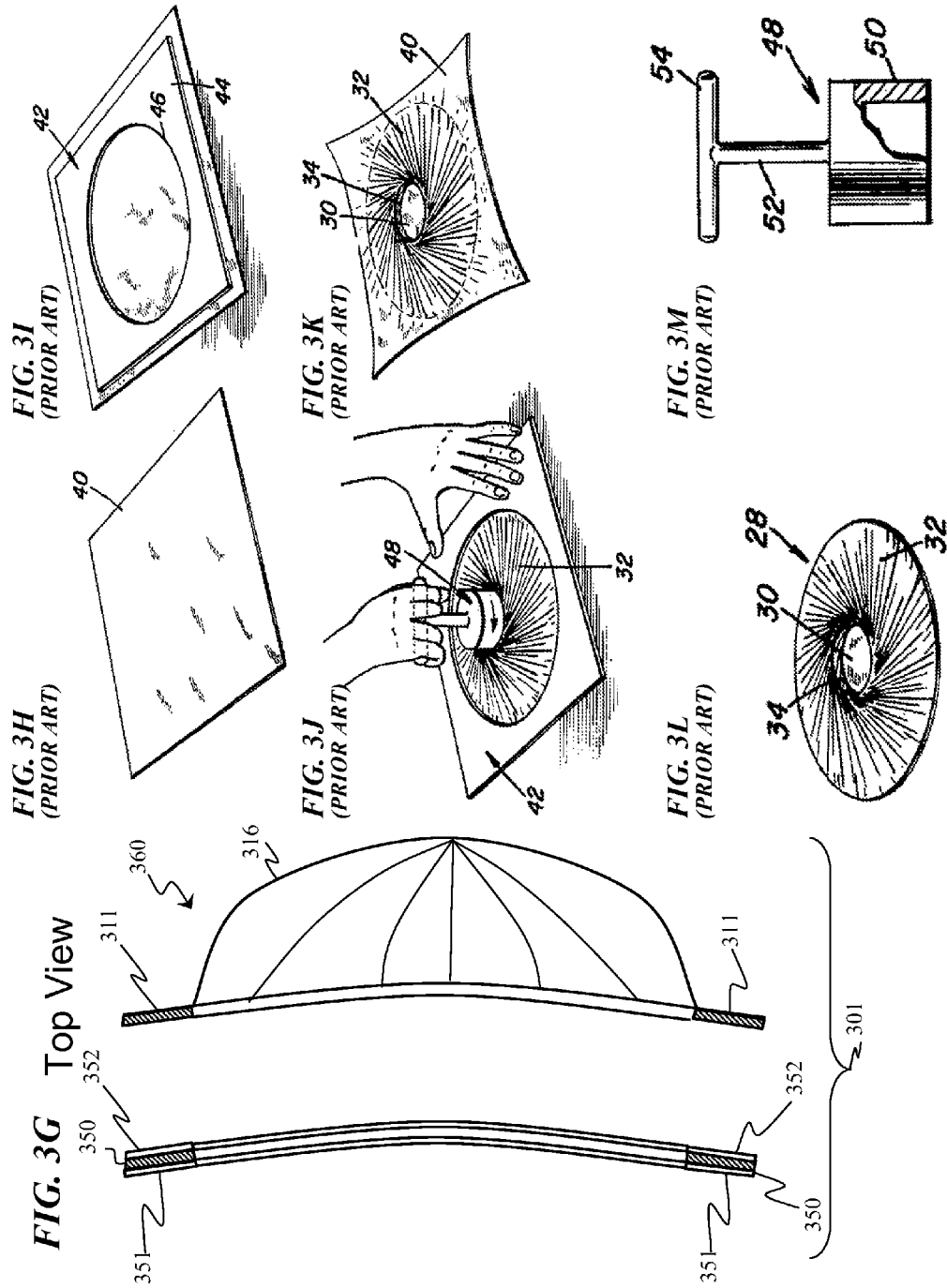
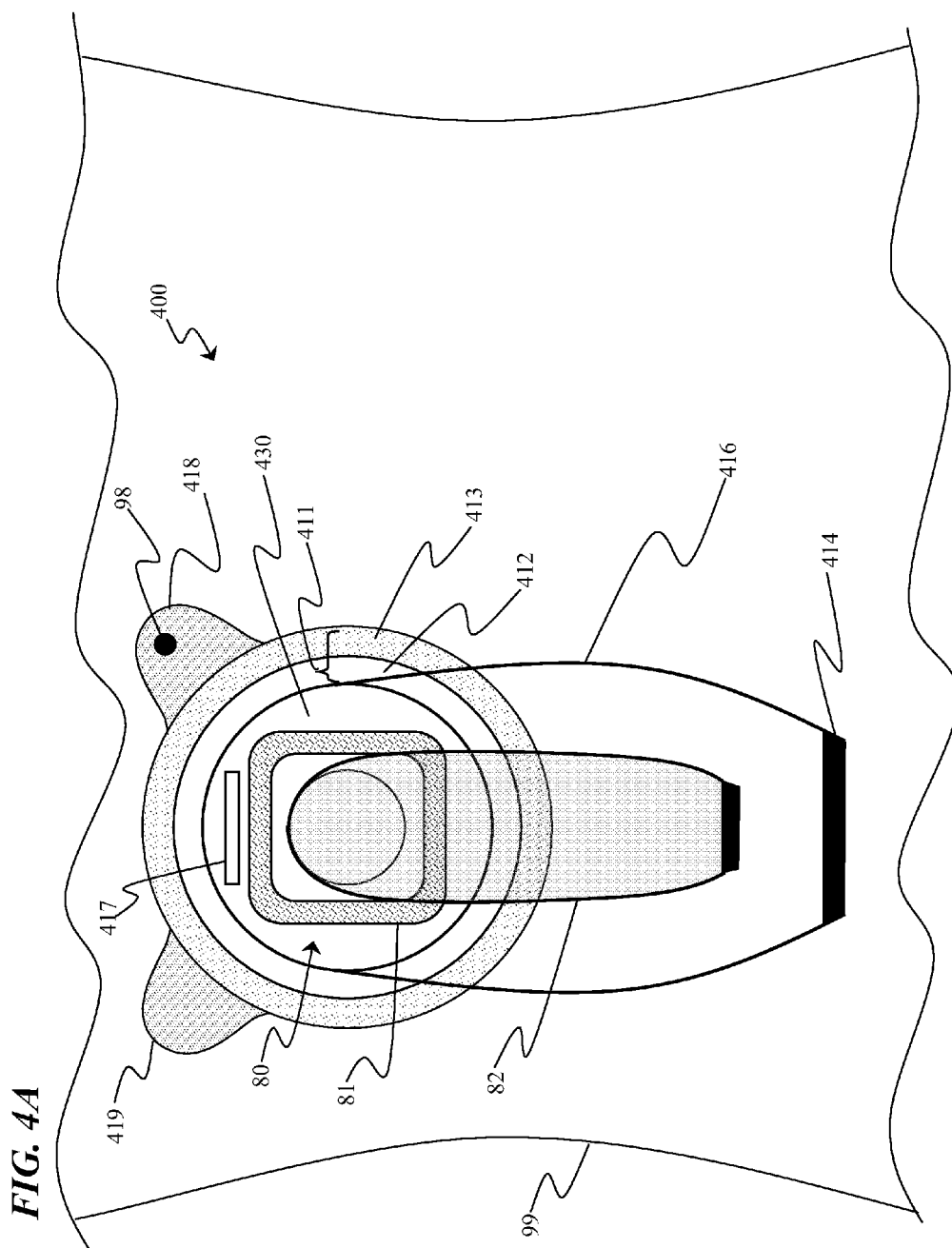


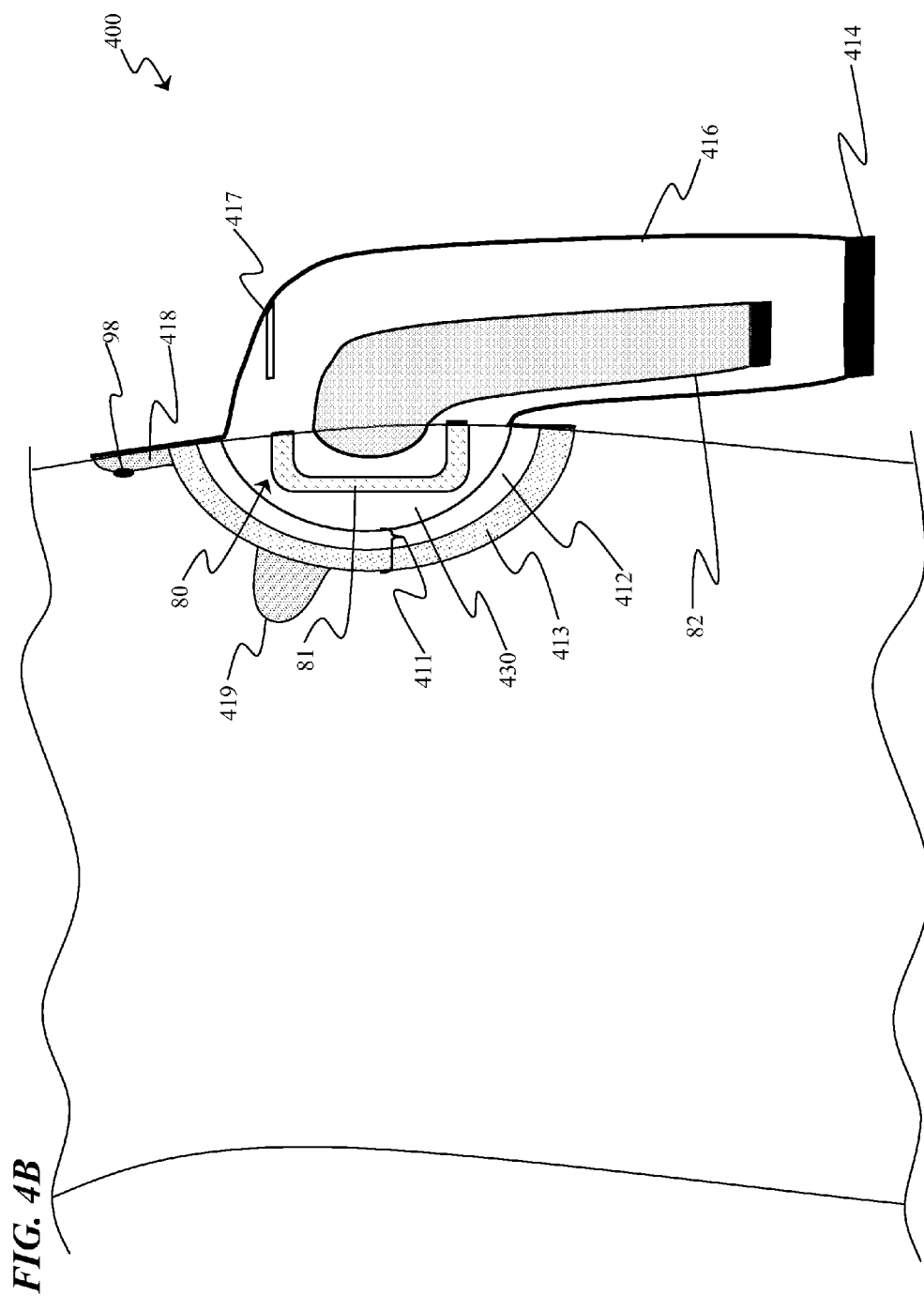
FIG. 3E

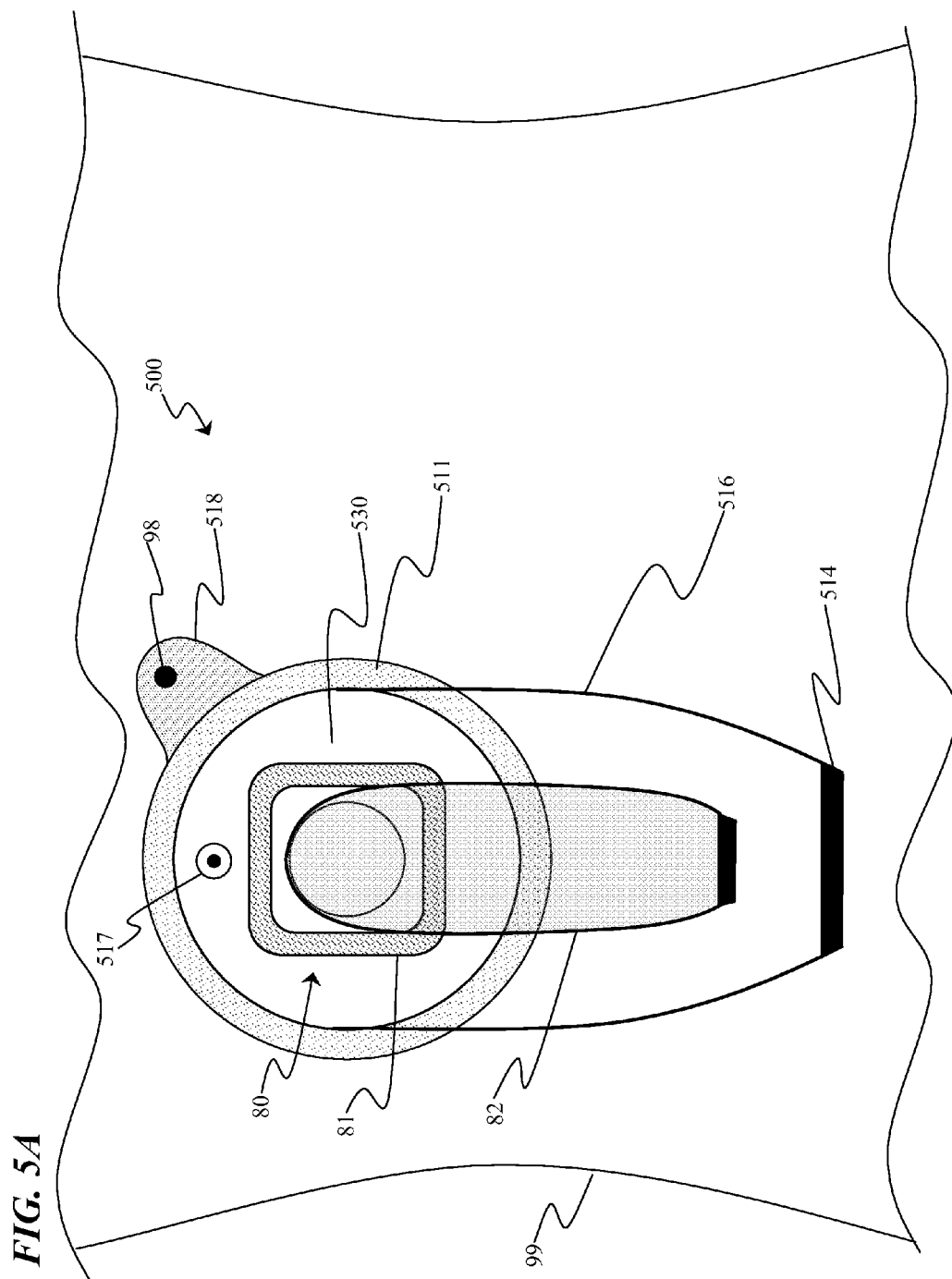
FIG. 3F

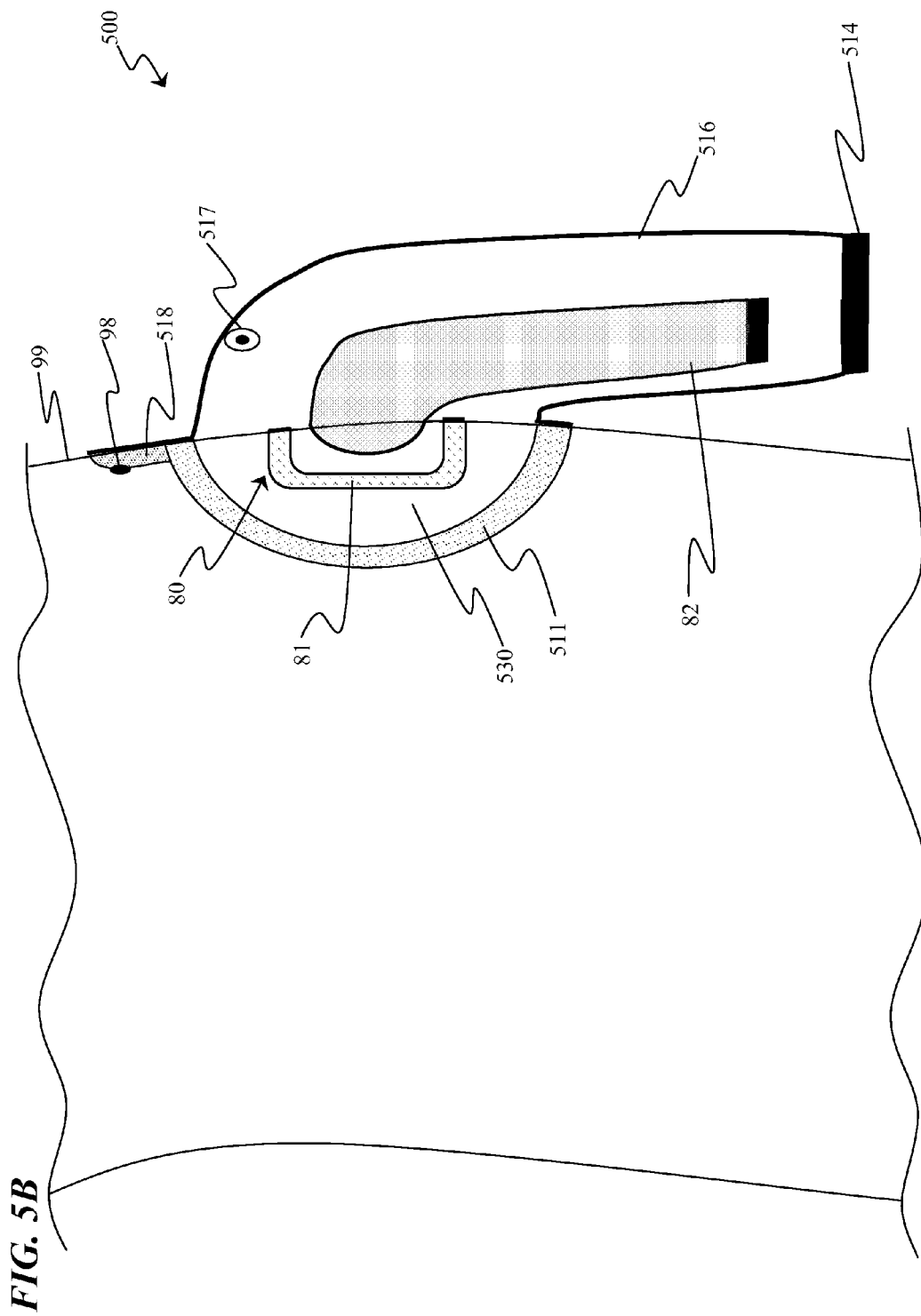


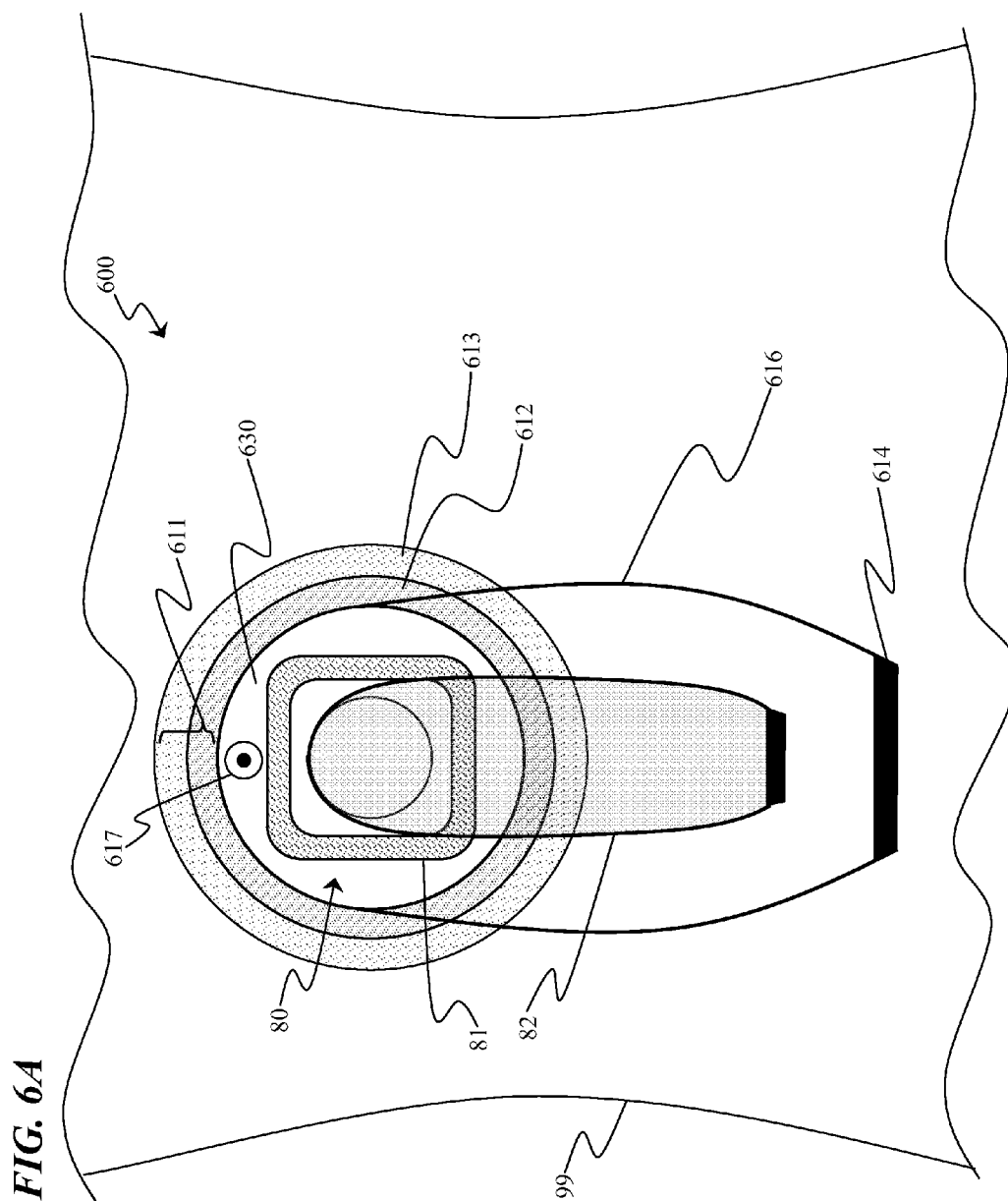












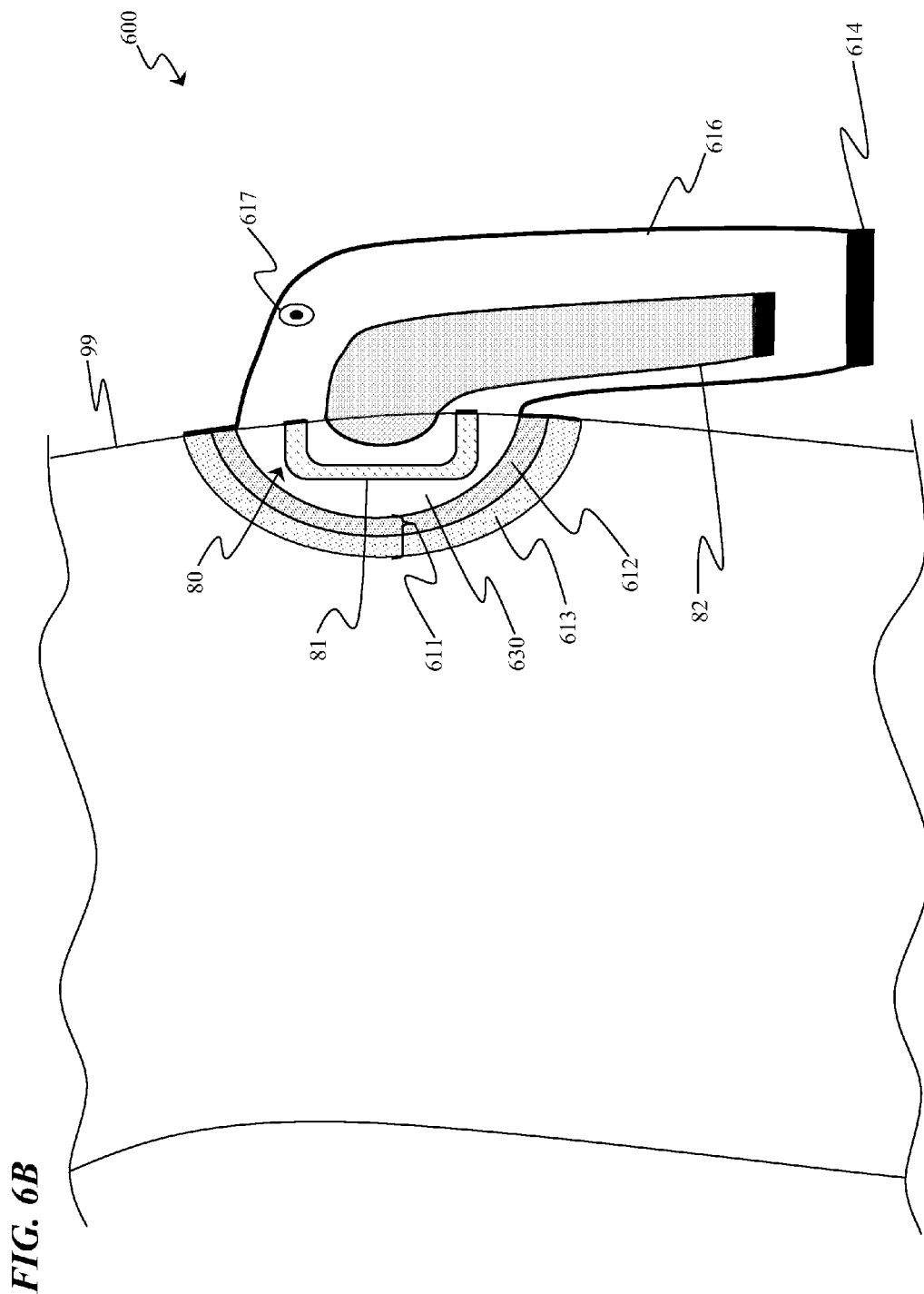
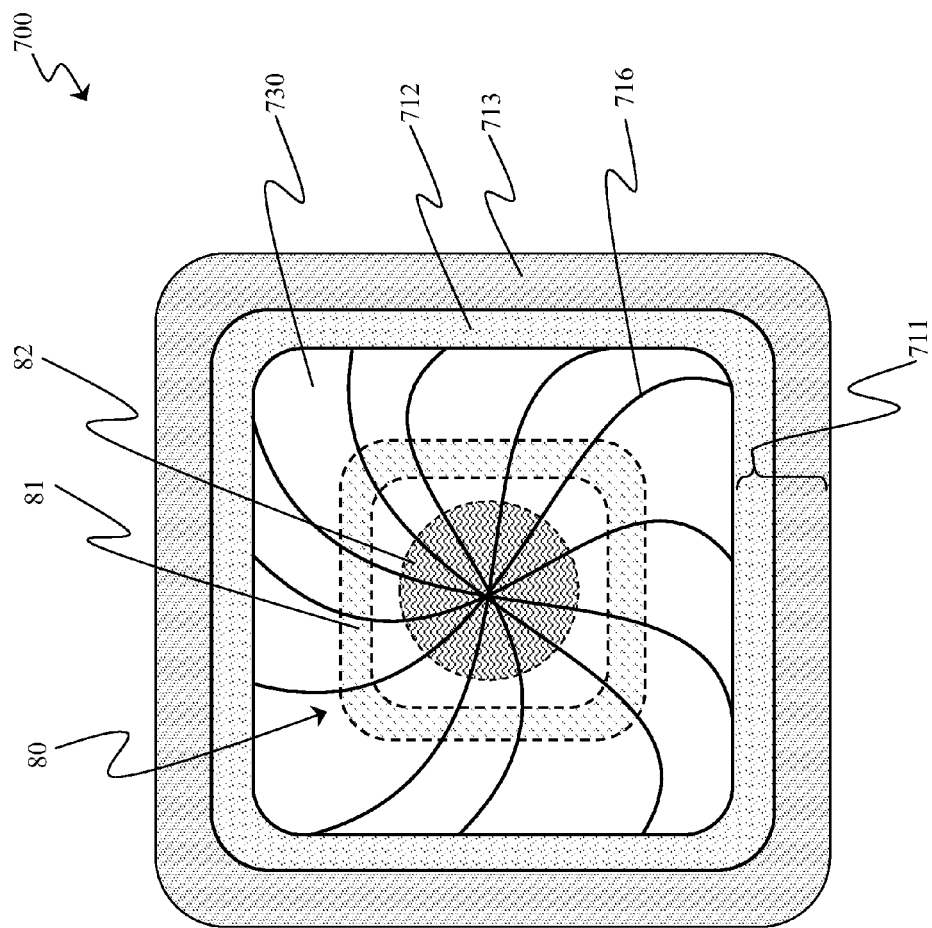


FIG. 7



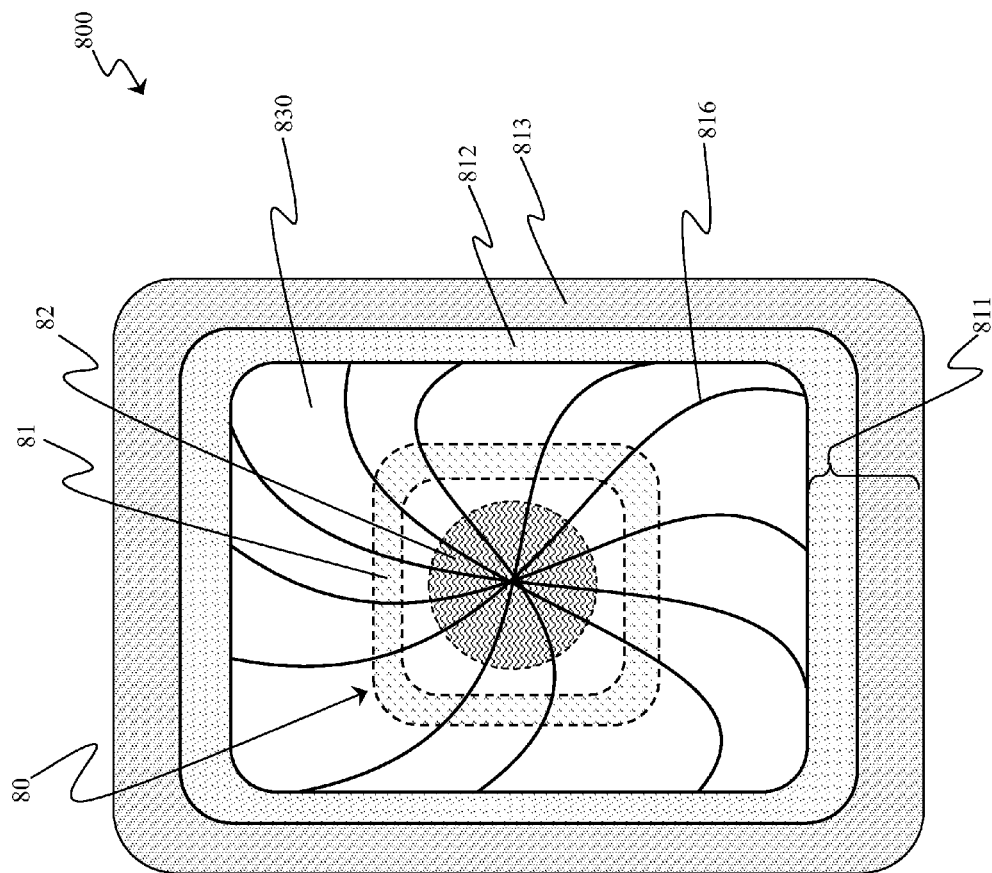


FIG. 8

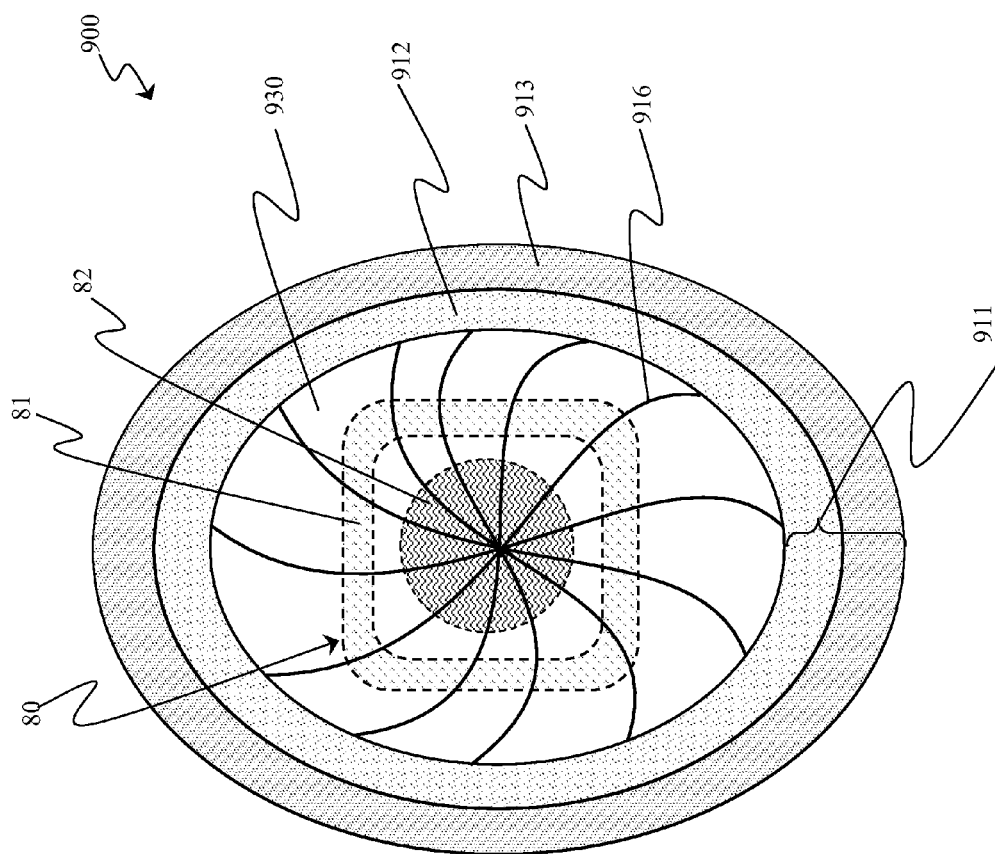


FIG. 9

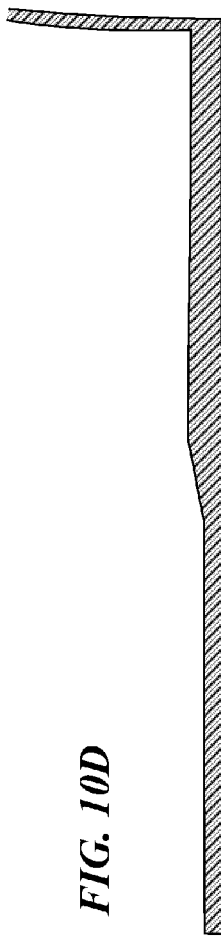
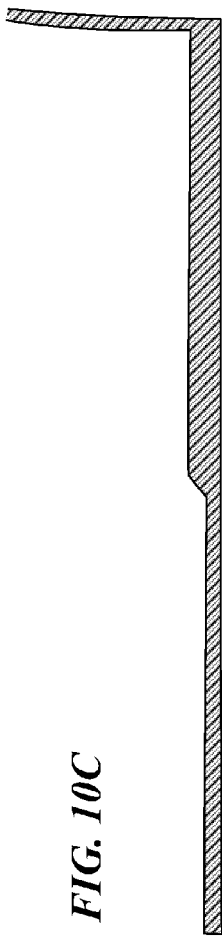
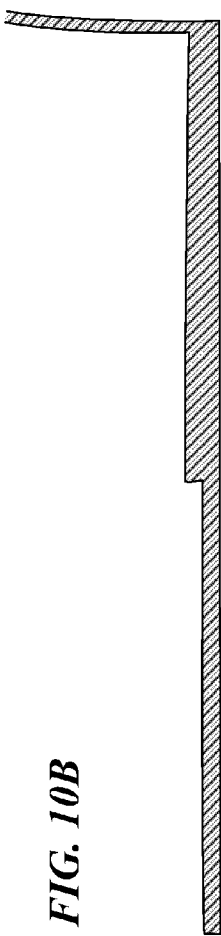
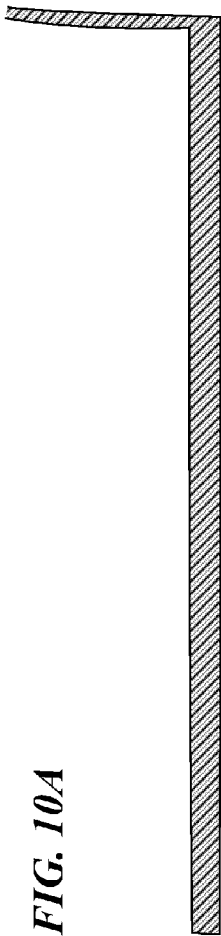


FIG. 10E

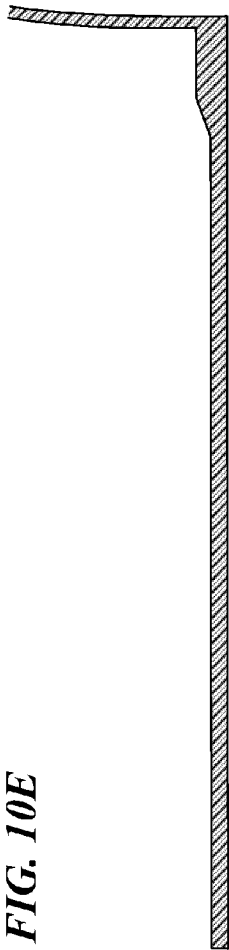


FIG. 10F

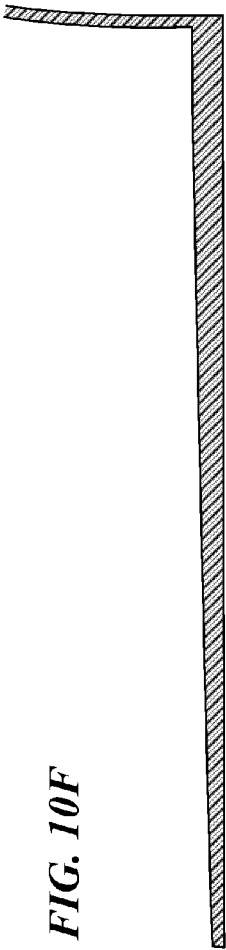
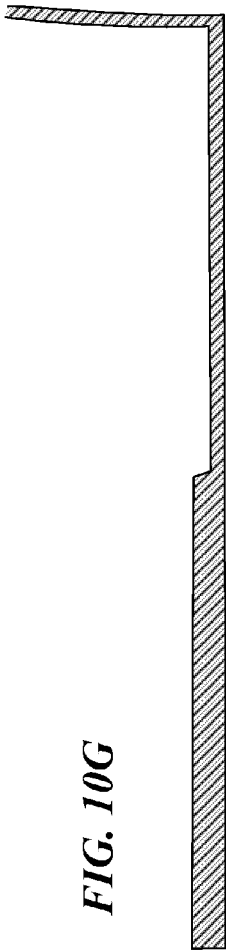


FIG. 10G



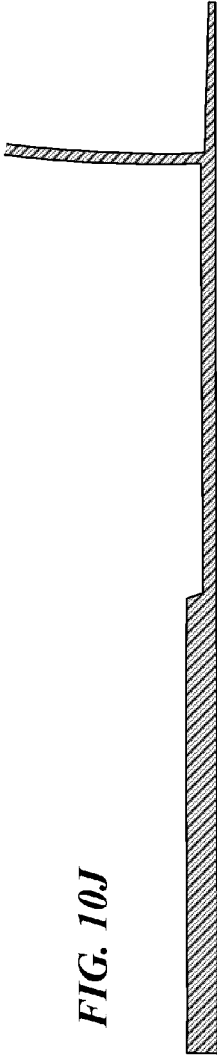
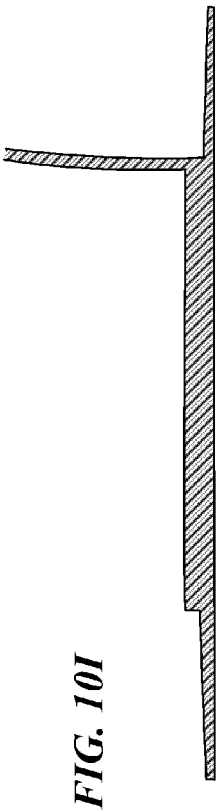
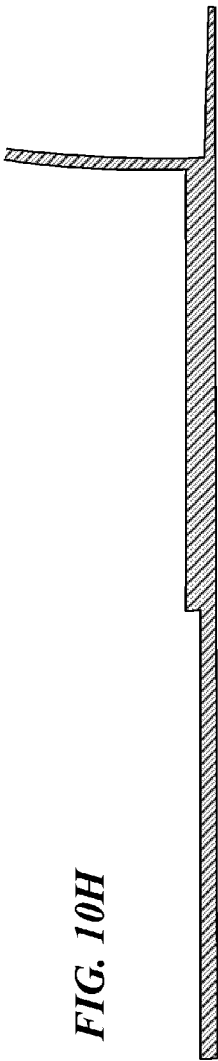


FIG. 11A

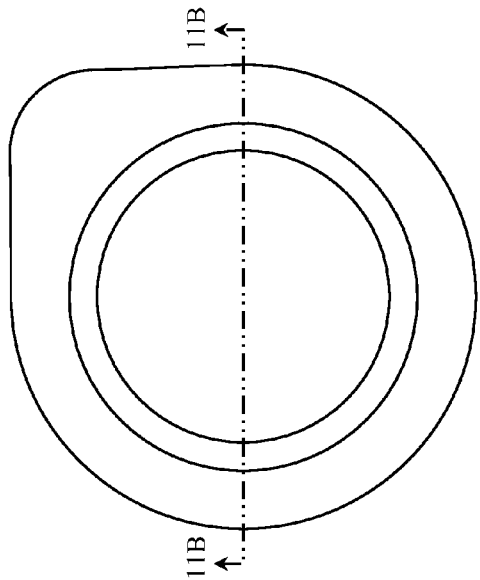


FIG. 12A

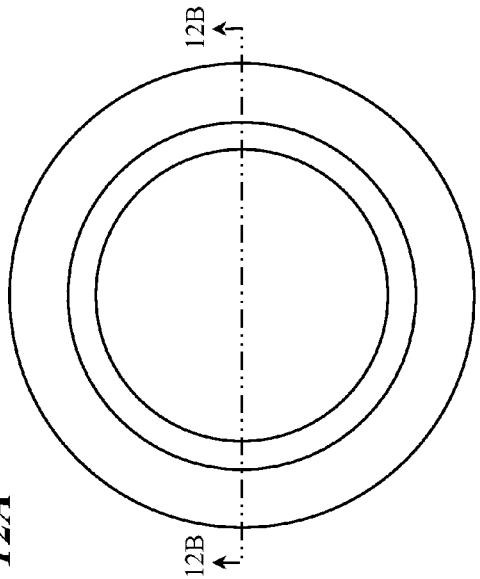


FIG. 11B

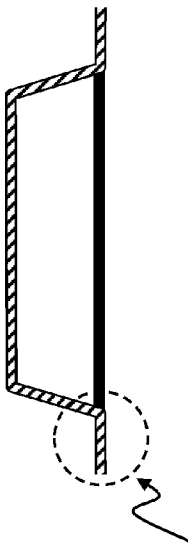


FIG. 12B

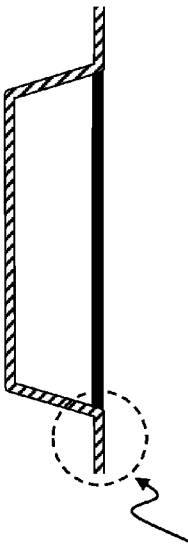


FIG. 13A

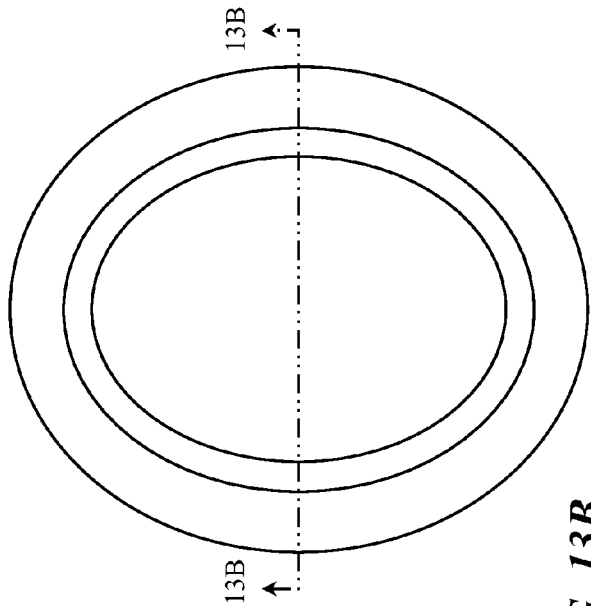
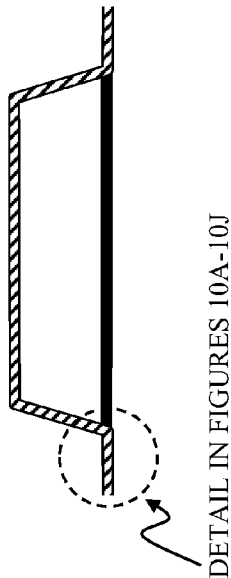


FIG. 13B



DETAIL IN FIGURES 10A-10J

FIG. 14A

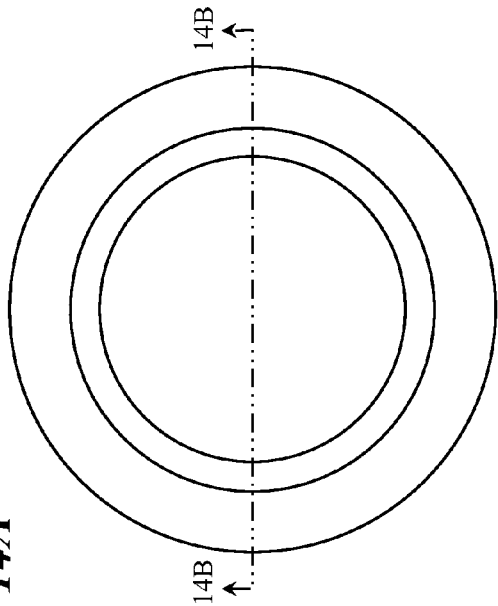
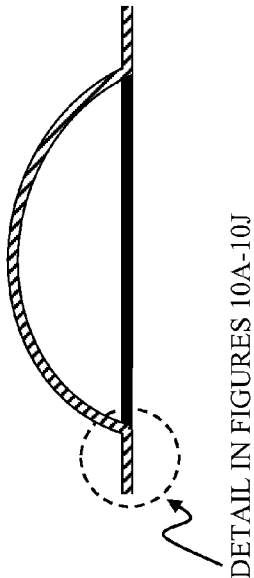


FIG. 14B



DETAIL IN FIGURES 10A-10J

FIG. 15A

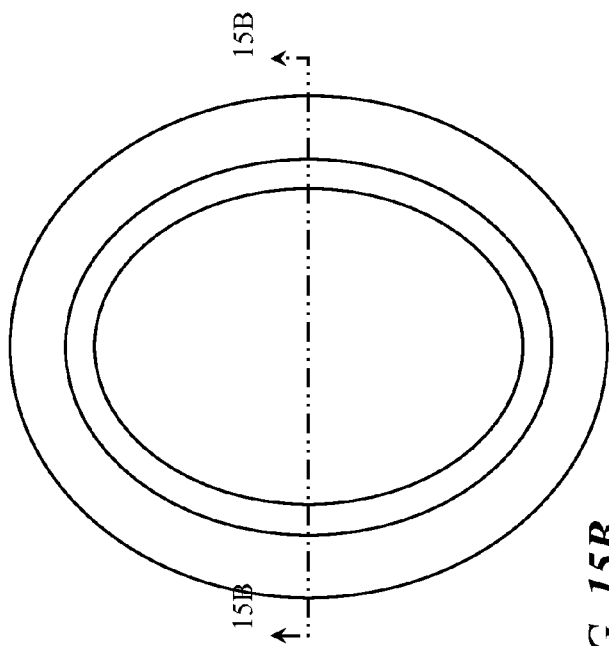
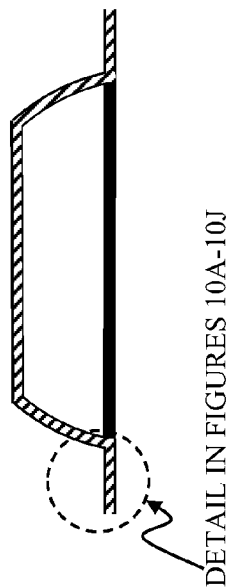


FIG. 15B



DETAIL IN FIGURES 10A-10J

FIG. 16A

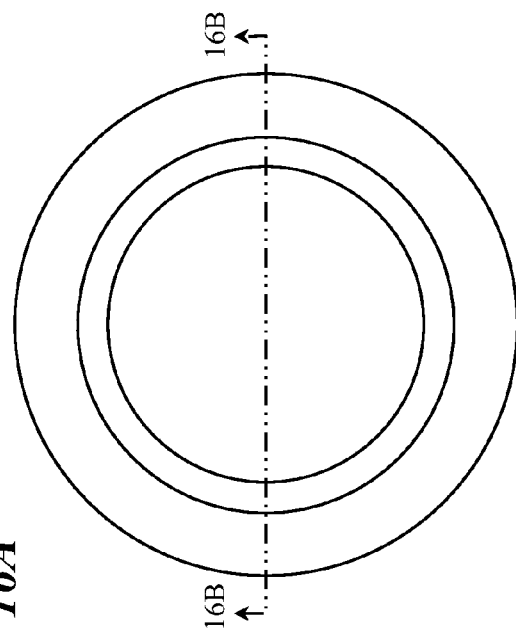
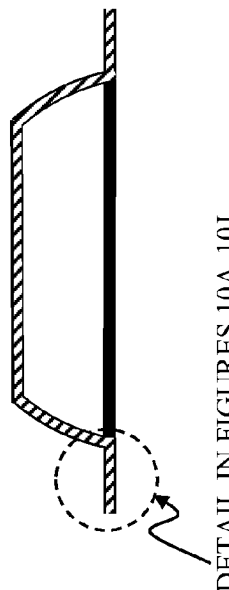
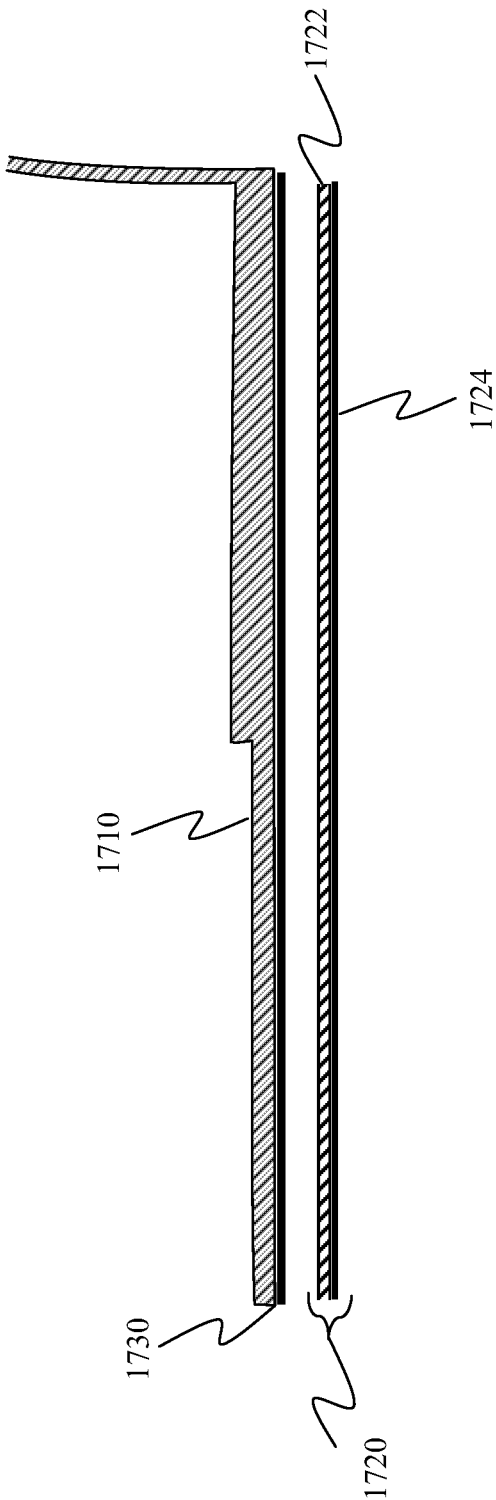


FIG. 16B



DETAIL IN FIGURES 10A-10J

FIG. 17



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**WATERPROOF COVER FOR OSTOMY BAG
AND METHOD****CROSS-REFERENCE TO RELATED
APPLICATIONS**

This application is a continuation-in-part of U.S. patent application Ser. No. 13/018,210 titled "OSTOMY BAG WATERPROOF COVER AND METHOD" filed Jan. 31, 2011 (which issued as U.S. Pat. No. 8,377,020 on Feb. 19, 2013), which claimed priority to U.S. Provisional Patent Application No. 61/434,348 titled "OSTOMY BAG WATER-PROOF COVER AND METHOD" filed Jan. 19, 2011, both of which are hereby incorporated herein by reference in their entirety.

FIELD OF THE INVENTION

The invention relates generally to ostomy bags and, more specifically, to covers for ostomy bags that can protect an ostomy bag during bathing or other activities.

BACKGROUND OF THE INVENTION

An ostomy is a surgical procedure in which an opening is created in a body for the discharge of waste. In this procedure, a passageway or stoma is made, typically through the abdominal wall and skin of the patient, and a portion of an intestine is surgically connected to the stoma so that waste matter can exit the body.

As used herein, "ostomy" is intended to cover all types surgical procedures in which a stoma is formed through the skin and is connected to an internal organ. Two common ostomies are "colostomy" wherein the colon is connected to the stoma, and "ileostomy" wherein the small intestine is connected to the stoma. Waste matter (fecal material) is uncontrollably discharged from the stoma. Consequently, the patient is required to wear an ostomy appliance, commonly known as an ostomy bag (or a stoma bag), wherein a flange of the ostomy bag is attached to the abdominal wall of the patient with an adhesive, and a plastic waste bag attached to the flange collects the waste discharged by the body. In some embodiments, the plastic waste bag can be removed from the flange and emptied as needed. A wide variety of ostomy bags are in general use.

While ostomy bags effectively collect waste matter, they present a number of problems. The actual collection bags are typically made of a plastic material that is somewhat transparent, which allows the collected waste matter in the bag to be partially visible, and which also has a tendency to stick to the body of the patient and to irritate the patient's skin. Ostomy bag covers have been designed to address these modesty and discomfort problems.

U.S. Pat. No. 4,439,191, which issued to Hogan Mar. 27, 1984 titled "Ostomy bag cover," is incorporated herein by reference. Hogan describes an ostomy bag cover for an ostomy bag of the type having an inlet, a connecting member for connecting the inlet in communication with a stoma on a wearer's body and a closeable outlet at the bottom of the ostomy bag for emptying the contents therefrom. The cover is in the form of a hollow body and includes a first aperture formed therein adapted to be disposed in registry with the inlet of the ostomy bag and to receive the connecting member therethrough. A second aperture is formed in the bottom of the hollow body between spaced side portions thereof and is adapted to be disposed in proximity with the outlet of the

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ostomy bag. A releasable fastener is mounted on the space sides for releasably closing the second aperture in the hollow body.

U.S. Pat. No. 4,983,171, which issued to Schirmer Jan. 8, 1991 titled "Comfortable ostomy pouch," is incorporated herein by reference. Schirmer describes an ostomy bag that is made with air cushion film so that the air bubbles are on the bag outside. Air cushion film is known as bubblepak in the industry. The bubbles afford a high degree of comfort to the person wearing the ostomy bag.

U.S. Pat. No. 5,026,362, which issued to Willett Jun. 25, 1991 titled "Ostomy bag holder and cover," is incorporated herein by reference. Willett describes an ostomy bag holder and cover of lightweight fabric material, comprises a waist encircling belt adapted to be adjustably secured about the waist of the user, and a pouch secured to the belt for holding and covering an ostomy bag, said pouch comprising a back panel having a cut-out therein for providing access from an ostomy bag to a stoma, and a front panel having releasable fastening means thereon for releasably attaching the front panel to the belt for covering an ostomy bag supported in the pouch. The front and back panels define a pocket at their lower ends for supporting the ostomy bag.

U.S. Pat. No. 5,607,412, which issued to Brown Mar. 4, 1997 titled "Ostomy bag cover," is incorporated herein by reference. Brown describes an ostomy bag cover that is formed of a single piece of a soft knit fabric, folded and sewn so that there are no rough edges in contact with the patient. The cover contains the ostomy bag and isolates the patient from direct contact of the plastic bag with the skin. The cover has a distal side panel and left and right proximal side panels that meet at a vertical midline on the patient side of the cover. The panels are left detached from one another from the top seam partway down the midline to define a vertical slot through which the fitting or flange of the ostomy bag protrudes. Another slot is provided along the bottom seam to accommodate a drain tube.

U.S. Pat. No. 5,759,180, which issued to Myhres Jun. 2, 1998 titled "Ostomy bag cover and assembly," is incorporated herein by reference. Myhres describes a cover for an ostomy bag which is opaque to camouflage waste in the ostomy bag. The cover is also moisture resistant to prevent the deterioration of the cover when exposed to moisture as well as to prevent the cover from separating from an ostomy bag when exposed to moisture. The cover may also include decorative patterns. The cover comprises a body portion and a neck portion. The body portion is shaped to substantially cover a body portion of a front side of an ostomy bag. The neck portion is shaped to substantially cover at least a lower part of a neck portion of a front side of an ostomy bag.

U.S. Pat. No. 5,843,054, which issued to Honig Dec. 1, 1998 titled "Ostomy bag cover," is incorporated herein by reference. Honig describes an ostomy bag cover for an ostomy bag of the type having an inlet, a connecting member for connecting the inlet in communication with a stoma on a wearer's body and a closable outlet at the bottom of the ostomy bag for emptying the contents therefrom. The cover is in the form of a hollow body and includes a ribbed aperture formed therein adapted to be disposed in close tolerance with the inlet of the ostomy bag and to receive the connecting member therethrough. Said ribbed aperture provides an improved fit of the ostomy bag cover in relation to the ostomy bag inlet thereby providing the wearer with greater comfort by reduced contact of the wearer's skin with the ostomy bag, the connecting member, or the ostomy inlet. A second aperture is formed in the bottom of the hollow body between spaced side portions thereof and is adapted to be disposed in

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proximity with the outlet of the ostomy bag. A releasable fastener is mounted on the space sides for releasably closing the second aperture in the hollow body.

United States Patent Application 2002/0010445 by Gunn filed Jul. 19, 2001 titled "Ostomy bag cover" is incorporated herein by reference. Gunn describes an ostomy bag cover for containing within an ostomy bag. The cover has a distal panel and a proximal panel with an optional belt attachment. The two panels are of similar size and shape and are placed together and joined, as by sewing for example, along their perimeters. However, the two (2) joined panels, forming a cover, have an opening at top for accepting the ostomy bag and an opening along the bottom, for emptying the ostomy bag.

United States Patent Application 2008/0208145 by McCulloch filed Feb. 26, 2007 titled "Disposable Shower Guard for Renal Access Catheter" is incorporated herein by reference. McCulloch describes a hemodialysis catheter, also known as a renal dialysis access catheter penetrates a patient's skin at an entrance site which is protected by associated bandaging, all of which needs to be protected from water when the patient takes a shower. The single use, disposable shower guard surrounds and encloses the catheter, the entrance site and the associated protective bandaging. A generally rectangular cutout in the guard is sized and oriented to surround the protective bandaging and leave a margin between the edge of the cutout and the protective bandaging so that the bandaging will not be disturbed when the guard is removed.

U.S. Pat. No. 2,815,883, which issued to Robins et al. Dec. 10, 1957 titled "Spirally Wound Covering For Popcorn Containers," is incorporated herein by reference. Robins et al. describe a cover for packages which is so constructed whereby it occupies a relatively small space when placed on a container and will open to greatly increase the effective size of the container. Robins et al. describe, in relation to prior-art FIGS. 3H to 3M, as follows: Referring now to prior-art FIGS. 3H through 3M, inclusive, it will be seen that there is illustrated the steps in forming the cover 28. Initially the cover 23 is in the form of a flat sheet of material 40 which is preferably square and formed of aluminum foil, although other desired materials may be utilized. In order to shape the cover 28 to meet the shape of the container 12 and at the same time to hold the sheet 40 in place during the cover forming operation, there is provided a pattern forming retainer 42. The retainer 42 is in the form of a flat plate. 44 which has a central circular opening 46 which is the pattern for making the cover 28. Referring now to FIG. 3M in particular, it will be seen that there is illustrated a forming member which is referred to in general by the reference numeral 48. The forming member 48 includes an inverted cup-shaped portion 50 which has extending upwardly therefrom a shank 52. The upper end of the shank 52 terminates in a handle 54. After the pattern forming retainer 42 has been positioned as illustrated in FIG. 3i, the forming member 48 is positioned in the exact center of the opening 46. With pressure being applied simultaneously to the pattern forming retainer 42 and to the forming member 48, the forming member 48 is rotated through a slight angle. This results in the twisting of the central part of the Sheet 40 about the forming member 48, as is best illustrated in FIG. 3J. As the sheet 40 is twisted, the spiral folds 32 are simultaneously formed. Inasmuch as the folds 32 are tightly turned about the forming member 48, when the forming member 48 is lifted from its position in FIG. 3J, the central portion 30 is pulled upwardly out of the plane of the outer part of the sheet 40. Thus, when the pattern forming retainer 42 has been removed, the central portion of the sheet 40 which will become the

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cover 28 is slightly upwardly bowed. After the pattern forming retainer 42 has been removed from the sheet 40, a suitable die (not shown) is utilized to cut the cover 28 of a size to fit from the sheet 40.

There is a need for an improved ostomy bag cover.

BRIEF SUMMARY OF THE INVENTION

An apparatus for covering an ostomy bag of a patient, the ostomy bag having an ostomy-bag flange, wherein the ostomy-bag flange adheres to the patient's skin surrounding a stoma. In some embodiments, this apparatus includes an ostomy-bag cover, wherein the ostomy-bag cover covers the ostomy bag and its ostomy-bag flange in order to prevent water from reaching the ostomy bag and its ostomy-bag flange. The ostomy-bag cover includes a body formed from a liquid-impermeable membrane, the body having a proximal end opening and a distal end opening; a cover-flange portion connected to the proximal end opening of the body, the cover-flange portion having a patient-skin-contact side and a distal side, wherein the patient-skin-contact side has a pressure-sensitive adhesive that releasably attaches the proximal side of the flange to the patient's skin surrounding the ostomy-bag flange and forms a water-tight seal to an area of the patient's skin that surrounds the ostomy-bag-flange; and a one-way exhaust vent, wherein the vent is operable to remove excess air within the ostomy-bag cover while the cover-flange portion is sealed to the patient's skin, wherein the vent prevents water from entering the ostomy-bag cover, whereby the ostomy-bag cover forms a water-tight cover over the ostomy bag and its ostomy-bag flange.

In some embodiments, the present invention provides an apparatus for covering an ostomy bag of a patient, where the ostomy bag has an ostomy-bag flange, and the ostomy-bag flange adheres to the patient's skin surrounding a patient's stoma. In some embodiments, the apparatus includes an ostomy-bag cover, such that the ostomy-bag cover covers the ostomy bag and its ostomy-bag flange in order to prevent water from reaching the ostomy bag and its ostomy-bag flange. The ostomy-bag cover includes a body formed from a liquid-impermeable membrane, the body having a proximal end opening and a distal end opening. In some embodiments, the present invention further includes a cover-flange portion connected to the proximal end opening of the body of the ostomy-bag cover, where the cover-flange portion has a patient-skin-contact side (proximal side) and a distal side, and where the patient-skin-contact side has a pressure-sensitive adhesive that releasably attaches the proximal side of the flange to the patient's skin surrounding the ostomy-bag flange and forms a watertight seal to an area of the patient's skin that surrounds the ostomy-bag-flange. In some embodiments, the present invention further includes a sealable exhaust vent, such that the vent is operable to remove excess air within the ostomy-bag cover while the cover-flange portion is sealed to the patient's skin, and where the vent prevents water from entering the ostomy-bag cover, in order that the ostomy-bag cover forms a watertight cover over the ostomy bag and its ostomy-bag flange.

In some embodiments, the present invention provides a method that includes making a covering for an ostomy bag of a patient, where the ostomy bag has an ostomy-bag flange, and the ostomy-bag flange adheres to the patient's skin surrounding a patient's stoma, where the ostomy-bag cover covers the ostomy bag and its ostomy-bag flange in order to restrict water from reaching the ostomy bag and its ostomy-bag flange. In some embodiments, the method includes providing a tubular body of the ostomy-bag cover made from a

liquid-impermeable membrane, where the tubular body has a proximal end opening and a distal end opening, and where the ostomy-bag cover covers the ostomy bag and its ostomy-bag flange in order to prevent water from reaching the ostomy bag and its ostomy-bag flange. In some embodiments, the present invention further includes providing a cover-flange portion connected to the proximal end opening of the tubular body, where the cover-flange portion has a patient-skin-contact side (proximal side) and a distal side, where the patient-skin-contact side has a pressure-sensitive adhesive that releasably attaches the proximal side of the flange to the skin of the patient and forms a watertight seal to an area of the patient's skin that surrounds the ostomy-bag flange. In some embodiments, the present invention further includes providing a resealable opening at the distal end of the tubular body. In other embodiments, the present invention includes adhering at least a first annular region of the proximal side of the cover-flange portion of the ostomy-bag cover to a patient with pressure-sensitive adhesive forming a watertight seal to the patient's skin, where the ostomy-bag cover forms a substantially waterproof cover over the ostomy bag and its ostomy-bag flange, and sealing the resealable opening to prevent water from entering the ostomy-bag cover.

In some embodiments, the present invention provides an apparatus for covering an ostomy bag of a patient, where the ostomy bag has an ostomy-bag flange, and where the ostomy-bag flange adheres to the patient's skin surrounding a stoma. In some embodiments, the apparatus includes a protective film means for covering the ostomy bag and its ostomy-bag flange in order to prevent water from reaching the ostomy bag and its ostomy-bag flange, where the cover (protective film means) is formed from a polymer film. In some embodiments, the present invention further includes a pressure-sensitive adhesive flange means for attaching the protective film means to a patient, where the pressure-sensitive adhesive flange means connects with the protective film means and releasably fastens the flange to the patient's skin surrounding the ostomy-bag flange and forms a water-resistant seal to the patient's skin. In other embodiments, the pressure-sensitive adhesive flange means contains an opening that is large enough for the flange to surround the ostomy-bag-flange without contacting the ostomy-bag-flange. In some embodiments, the present invention further includes a folding means for flattening (such as shown in FIGS. 3H through 3M) the protective film means and pressure-sensitive adhesive flange means for distribution, such that the protective film means and pressure-sensitive adhesive flange means are substantially flat before use and where the protective film means unfolds to fit over the ostomy bag and its ostomy-bag flange.

In some embodiments, the present invention provides an apparatus kit for covering an ostomy bag of a patient, where the ostomy bag has an ostomy-bag flange, and where the ostomy-bag flange adheres to the patient's skin surrounding a stoma. In some embodiments, the apparatus kit includes an ostomy-bag-cover body, where the ostomy-bag-cover body includes a protective covering formed from a liquid-impermeable membrane, wherein the protective covering is substantially flat before use, and wherein the protective covering unfolds to fit over the ostomy bag and its ostomy-bag flange, and the ostomy-bag-cover body further includes a cover-flange portion connected to the protective covering. These embodiments of the present invention also include an adhesive-attachment band, where the adhesive-attachment band has a first surface coated with a pressure-sensitive adhesive, and a second surface coated with a pressure-sensitive adhesive, and where the adhesive-attachment band is shaped approximately the same as the cover-flange. The pressure-

sensitive adhesive on the first side of the adhesive-attachment band is covered by a first removable piece of release film, and the pressure-sensitive adhesive on the second side of the adhesive-attachment band is covered by a second removable piece of release film. The adhesive-attachment band releasably attaches the cover-flange to an area of the patient's skin surrounding the ostomy-bag flange and forms a watertight seal to an area of the patient's skin that surrounds the ostomy-bag-flange.

BRIEF DESCRIPTION OF THE FIGURES

Each of the items shown in the following brief description of the drawings represents one or more aspects of some embodiments of the present invention.

FIG. 1A is a front perspective view of an ostomy-bag-cover system **100**, according to some embodiments of the present invention.

FIG. 1B is a side perspective view of an ostomy-bag-cover system **100**, according to some embodiments of the present invention.

FIG. 2A is a front perspective view of an ostomy-bag-cover system **200**, according to other embodiments of the present invention.

FIG. 2B is a side perspective view of an ostomy-bag-cover system **200**, according to other embodiments of the present invention.

FIG. 3A is a front perspective view of an ostomy-bag-cover system **300**, according to other embodiments of the present invention.

FIG. 3B is a side perspective view of an ostomy-bag-cover system **300**, according to other embodiments of the present invention.

FIG. 3C is a top cross-sectional view of an ostomy-bag-cover system **300** showing an enclosing cover **345**, according to other embodiments of the present invention.

FIG. 3D is a back view of an ostomy-bag-cover system **300** showing an enclosing cover **345**, according to other embodiments of the present invention.

FIG. 3E is a top cross-sectional view of an ostomy-bag-cover system **300**, according to other embodiments of the present invention.

FIG. 3F is a back view of an ostomy-bag-cover kit system **301**, according to other embodiments of the present invention.

FIG. 3G is a top cross-sectional view of an ostomy-bag-cover system **301**, according to other embodiments of the present invention.

FIG. 3H is a perspective view of a sheet from which the cover is formed, according to some embodiments.

FIG. 3I is a perspective view showing a pattern forming retainer positioned on the sheet as a first step in making the cover.

FIG. 3J is a perspective view showing a forming member engaged with the center of the sheet in the center of the pattern, the forming member having been twisted about its axis to produce the spiral folds in the sheet.

FIG. 3K is a perspective view of the sheet showing it after the spiral folds have been formed therein.

FIG. 3L is a perspective view of the cover after it has been cut from the sheet.

FIG. 3M is an enlarged elevational view of the forming member with a portion thereof broken away in order to clearly illustrate the details thereof.

FIG. 4A is a front perspective view of an ostomy-bag-cover system **400**, according to some embodiments of the present invention.

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FIG. 4B is a side perspective view of an ostomy-bag-cover system 400, according to some embodiments of the present invention.

FIG. 5A is a front perspective view of an ostomy-bag-cover system 500, according to other embodiments of the present invention.

FIG. 5B is a side perspective view of an ostomy-bag-cover system 500, according to other embodiments of the present invention.

FIG. 6A is a front perspective view of an ostomy-bag-cover system 600, according to other embodiments of the present invention.

FIG. 6B is a side perspective view of an ostomy-bag-cover system 600, according to other embodiments of the present invention.

FIG. 7 is a front perspective view of an ostomy-bag-cover system 700, according to other embodiments of the present invention.

FIG. 8 is a front perspective view of an ostomy-bag-cover system 800, according to other embodiments of the present invention.

FIG. 9 is a front perspective view of an ostomy-bag-cover system 900, according to other embodiments of the present invention.

FIG. 10A is a cross-sectional view of an ostomy-bag-cover flange, according to some embodiments of the present invention.

FIG. 10B is a cross-sectional view of an ostomy-bag-cover flange, according to other embodiments of the present invention.

FIG. 10C is a cross-sectional view of an ostomy-bag-cover flange, according to other embodiments of the present invention.

FIG. 10D is a cross-sectional view of an ostomy-bag-cover flange, according to other embodiments of the present invention.

FIG. 10E is a cross-sectional view of an ostomy-bag-cover flange, according to other embodiments of the present invention.

FIG. 10F is a cross-sectional view of an ostomy-bag-cover flange, according to other embodiments of the present invention.

FIG. 10G is a cross-sectional view of an ostomy-bag-cover flange, according to other embodiments of the present invention.

FIG. 10H is a cross-sectional view of an ostomy-bag-cover flange, according to other embodiments of the present invention.

FIG. 10I is a cross-sectional view of an ostomy-bag-cover flange, according to other embodiments of the present invention.

FIG. 10J is a cross-sectional view of an ostomy-bag-cover flange, according to other embodiments of the present invention.

FIG. 11A is a top view of an ostomy-bag-cover, according to some embodiments of the present invention.

FIG. 11B is a side cross-sectional view of an ostomy-bag-cover, according to some embodiments of the present invention.

FIG. 12A is a top view of an ostomy-bag-cover, according to other embodiments of the present invention.

FIG. 12B is a side cross-sectional view of an ostomy-bag-cover, according to other embodiments of the present invention.

FIG. 13A is a top view of an ostomy-bag-cover, according to other embodiments of the present invention.

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FIG. 13B is a side cross-sectional view of an ostomy-bag-cover, according to other embodiments of the present invention.

FIG. 14A is a top view of an ostomy-bag-cover, according to other embodiments of the present invention.

FIG. 14B is a side cross-sectional view of an ostomy-bag-cover, according to other embodiments of the present invention.

FIG. 15A is a top view of an ostomy-bag-cover, according to other embodiments of the present invention.

FIG. 15B is a side cross-sectional view of an ostomy-bag-cover, according to other embodiments of the present invention.

FIG. 16A is a top view of an ostomy-bag-cover, according to other embodiments of the present invention.

FIG. 16B is a side cross-sectional view of an ostomy-bag-cover, according to other embodiments of the present invention.

FIG. 17 is a cross-sectional view of an ostomy-bag-cover flange and adhesive tape, according to some embodiments of the present invention.

DETAILED DESCRIPTION OF THE INVENTION

Although the following detailed description contains many specifics for the purpose of illustration, a person of ordinary skill in the art will appreciate that many variations and alterations to the following details are within the scope of the invention. Accordingly, the following preferred embodiments of the invention are set forth without any loss of generality to, and without imposing limitations upon the claimed invention. Further, in the following detailed description of the preferred embodiments, reference is made to the accompanying drawings that form a part hereof, and in which are shown by way of illustration specific embodiments in which the invention may be practiced. It is understood that other embodiments may be utilized and structural changes may be made without departing from the scope of the present invention.

The leading digit(s) of reference numbers appearing in the Figures generally corresponds to the Figure number in which that component is first introduced, such that the same reference number is used throughout to refer to an identical component which appears in multiple Figures. Signals and connections may be referred to by the same reference number or label, and the actual meaning will be clear from its use in the context of the description.

As used herein, the term “ostomy appliance,” the term “ostomy bag” and the term “stoma bag” are synonymous. As noted above, an ostomy bag typically has a flange that is attached to the abdominal wall of the patient with an adhesive, and a plastic waste bag, attached to the flange, that collects the waste discharged by the body. In some embodiments, the plastic waste bag can be removed from the flange and emptied as needed, and then reattached to the flange for reuse.

As used herein, the term “waterproof” means keeping an item completely dry for a period of at least 60 minutes while submerged in water or exposed to water spray. As used herein, the term “watertight” means keeping an item dry for at least at least 30 minutes while exposed to water spray and at least 5 minutes while submerged in water. As used herein, the term “water-resistant” means keeping an item dry for at least 15 minutes while exposed to casual water contact, such as water spray in a shower.

As used herein, the term “band” means the substantially flat area of material between two geometric shapes, such as the area of material between two substantially concentric circles (also known as an annulus), the area of material

between two substantially concentric ovals, the area between two substantially concentric rectangles, the area of material between two substantially concentric rectangles with rounded corners, the area of material between a circle/oval and a square/rounded square, or between any two geometric shapes where the inner shape is the edge of the material that surrounds an opening and the outer shape is the other outside edge of the material that surrounds the inner shape. The term “band” also includes the flat area of material between two geometric shapes where the shapes are not substantially concentric such as is the case when one side of the band is wider than another side of the band (i.e., wherein the opening is not centered within the material).

Problems are encountered with ostomy bag usage when showering. A person can do any of several things with the ostomy bag when he or she showers: the patient can wear the ostomy bag, getting it wet. The ostomy bag needs to be dried or changed after the shower to prevent moisture against the skin, causing possible chafing and skin irritation. Persons can use a hair dryer to dry the external bag. The hot air from the hair dryer causes the ostomy-bag flange adhesive as well as the fabric of the bag to wear out prematurely. Some people wash and dry the original stoma bag for reuse.

A person can remove the bag before the shower. If the person chooses to use nothing as a bag, then the excrement can flow freely during the shower and is messy and unsanitary.

In some embodiments, the present invention includes a one-piece waterproof impermeable stoma-bag cover with a flange having a very flexible flange edge for better sealing capability. The impermeable plastic stoma-bag cover encloses the fabric stoma bag and the stoma bag's flange, and the flange of the stoma-bag cover is adhesively attached to the skin surrounding the flange of the stoma bag. The impermeable stoma-bag cover fits over the various styles of stoma bags and their flanges. In some embodiments, the impermeable stoma-bag cover and the cover's flange form a single unit that comes in two sizes, one for children and one for adults. After showering, the person typically removes and disposes the impermeable cover and flange. The impermeable stoma-bag cover of the present invention, with its flange, is convenient and efficient to use. Use of the stoma-bag cover minimizes the time it takes the person having a stoma bag to get ready after showering (since it is not necessary to change or dry the original stoma bag and flange); minimizes wear and tear and extends the life of the original stoma bag and its flange because it is no longer necessary to dry the original stoma bag and flange. The stoma-bag cover keeps the stoma bag dry. Use of the stoma-bag cover allows less frequent changing of the original stoma and flange, which reduces chance of skin irritation. Use of the stoma-bag cover removes some of the risk of a possible leakage that can happen when water or heat are used on the stoma bag's flange.

In other embodiments, the present invention includes a water-impermeable cover. The water-impermeable cover has a non-irritating adhesive around the open circle on the back side which adheres to the left or right side of abdomen. In some embodiments, the water-impermeable cover has optional flaps along sides to be placed over the navel (umbilicus). This is to be used if the edge of the impermeable bag ends up close to the navel, in that case the flap is put over the navel to seal off any chances of water getting into the navel and then leaking into the bag. If a person does not need the flap, the flap can be cut off.

In some embodiments, the present invention includes a waterproof cover that surrounds the ostomy bag as well as the

ostomy bag's flange in one easy step, wherein the cover is a one-piece bag and adhesive flange. Attributes of the cover include:

A. One doesn't have to change stoma bags and flanges as often because the water proof bag keeps it all dry. The appliance (stoma bag) lasts longer when the flange does not get wet.

B. One doesn't have to shower without one's appliance. This eliminates having to clean up an unsanitary bathtub after a shower.

C. One saves time and there is no mess since one is not changing one's stoma appliance.

D. One will save money by not having to change one's appliance as often.

E. There will be less skin irritation due to less stoma appliance changes per week.

F. It is disposable, making it quick and easy to use and throw away.

G. It is affordable, being much less expensive than a replacement stoma bag.

H. The stoma bag flange stays dry so one doesn't have to use hairdryer to dry the stoma bag flange after showering. This saves a lot of time getting ready for the day.

I. It allows for easy, quick daily showering.

J. It is convenient.

K. It is simple to put on.

L. One doesn't have to wash the stoma bag out for reuse.

FIG. 1A is a front perspective view and FIG. 1B is a side perspective view of an ostomy-bag cover system **100**, according to some embodiments of the present invention. In some embodiments, the ostomy bag cover **100** includes a flange **111** and an impermeable plastic bag cover **116**. The impermeable plastic bag cover **116** is attached to the inner-portion **112** of the flange **111**, and the outer portion of the proximal surface of the flange **111** is covered with a pressure-sensitive adhesive **113** that adheres to the abdomen of the patient **99**. In some embodiments, the adhesive covered region of the ostomy-bag-flange **113** is 1 cm. wide. In other embodiments, the adhesive covered region of the ostomy-bag-cover flange **113** is less than 1 cm wide. In other embodiments, the adhesive covered region of the ostomy-bag-flange **113** is more than 1 cm wide.

The ostomy-bag cover covers an ostomy bag **80**, wherein the ostomy bag is any of several commercially available ostomy bags. The ostomy bag typically includes a stoma flange **81** and a stoma bag **82** attached to the stoma flange and wherein a proximal surface of stoma flange **81** is covered with a pressure-sensitive adhesive that adheres to the abdomen of the patient **99**. In some embodiments, the ostomy bag cover **100** includes tabs **118** and **119** used to cover the navel **98** of the patient **99** if the person's navel is near the outer portion of the ostomy bag cover flange **113**. The appropriate tab is used depending of which side of the body the stoma is located, wherein, in some embodiments, the unneeded tab can be removed. In some embodiments, both tabs can be removed if neither is needed. In some embodiments, the inside opening of the ostomy bag cover flange **111** is sized large enough that an open space **130** is formed between the ostomy-bag flange **81** and the ostomy-bag-cover flange **111**. When attached, the ostomy bag cover provides a water-impermeable covering for the ostomy bag, such that in some embodiments, the patient can shower while wearing the ostomy bag cover and not have the ostomy bag get wet.

FIG. 2A is a front perspective view and FIG. 2B is a side perspective view of an ostomy-bag cover system **200**, according to other embodiments of the present invention. The ostomy-bag cover **200** includes a flange **211** which is attached

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to a flexible plastic film cover **216**. The flange **211** removably attaches to the abdomen of the patient **99** with an adhesive on the proximal side of the flange **211** wherein the seal formed by the flange and the skin of the patient is substantially watertight. Further, in other embodiments of the present invention, a tab **218** is attached to the ostomy-bag-cover flange **211** such that the tab **218** is used to cover and seal the perimeter of the area around the navel **98** of the patient **99** when the stoma is located near the navel such that ostomy-bag-cover flange **211** may not adequately seal all of the perimeter of the area around an ostomy bag (not shown) due to the uneven surface of the skin in the proximity of the navel. If not needed, the ostomy-bag-cover tab **218** can be removed, either by cutting it off, or in some embodiments, torn along perforations at the connection of the tab and the ostomy-cover flange **211**. The ostomy-bag cover **200** keeps water away from the ostomy bag (not shown) so that in some embodiments, the patient can shower or bathe without getting his or her ostomy bag wet. In some embodiments, the ostomy-bag cover is single-use, and is removed and disposed of after the patient bathes or showers.

FIG. 3A is a front perspective view and FIG. 3B is a side perspective view of an ostomy-bag cover system **300**, according to other embodiments of the present invention. The ostomy-bag cover **300** includes a flange **311** and a liquid-impermeable flexible cover **316**. In some embodiments, the liquid-impermeable flexible cover folds flat (such as shown in FIGS. 3H through 3M) for packaging and distribution, and unfolds to cover an ostomy bag (not shown). In some embodiments, this unfolding can be similar to that used in "Jiffy Pop" package tops, as described in U.S. Pat. No. 2,815,883 to Robins et al. issued Dec. 10, 1957 titled "Spirally Wound Covering For Popcorn Containers".

In some embodiments, the ostomy-bag-cover flange **311** includes an inner region **312** and an outer region **313**, wherein the flange inner region **312** is attached to the liquid-impermeable flexible cover **316** and the proximal (patient-skin) side of the flange **311** is coated with an adhesive that releasably fastens the ostomy-bag cover to the abdominal skin of the patient **99**. The ostomy-bag cover when attached to the patient forms a substantially watertight covering over the ostomy bag.

FIG. 3C is a top cross-sectional view and FIG. 3D is a back view of the ostomy-bag-cover system **300**, according to some embodiments of the present invention. In other embodiments, the ostomy-bag-cover flange **311** is coated with an adhesive that releasably fastens the ostomy-bag cover to the abdominal skin of the patient **99**, forming a watertight seal between the flange **311** and the skin of the patient **99**. In some embodiments, the adhesive coated flange is protected with at least one thin, easily removable layer of material during shipping to prevent the flange adhesive from adhering to anything prior to being attached to the patient's skin. In some embodiments, the protective material can be paper. In other embodiments, the protective material can be plastic or other thin film. To attach the ostomy-bag cover, the patient first removes the protective layer **341** from the inner region of the ostomy-bag-cover flange **311**, and then positions the ostomy-bag cover in the desired location on his or her abdominal skin. The adhesive on the inner region of the flange holds the ostomy-bag cover to the patient's skin and aids in the positioning of the ostomy-bag cover. Once the ostomy-bag cover is positioned as desired, the protective layer **342** from the outer region of the flange **311** is removed and the flange is firmly pressed onto the patient's skin, forming a watertight seal. In the process of attaching the ostomy-bag cover, the ostomy-bag cover may have to be repositioned one or more times, or may flex in

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handling, resulting in wrinkles in the flange and possibly areas on the flange where the adhesive has become weak. In such cases, the needed watertight seal between the flange and the skin of the patient may be compromised. The adhesive on the outer region of the flange, which is not exposed until the ostomy-bag cover is positioned on the patient's skin, ensures a good seal between the flange and the skin. In some embodiments, each ostomy-bag cover is enclosed in its own wrapper **345** made of, e.g., paper, cardboard, plastic, foil and/or the like.

In some embodiments, each of the protective layers **341** and **342** is a single piece of material. In other embodiments, either or both of the protective layers is formed from two pieces of material as shown in FIG. 3D. This allows the layer of protective material to be more easily removed, especially the layer of protective material **342** that covers the outer region of the flange, since this layer of protective material is removed after the ostomy-bag cover is partially attached to the patient's abdominal skin with the adhesive on the inner region of the ostomy-bag-cover flange. In some embodiments of the present invention, the ostomy-bag-cover flange **311** is one centimeter wide. In other embodiments, the ostomy-bag-cover flange **311** is wider than one centimeter. In other embodiments, the ostomy-bag-cover flange **311** is narrower than one centimeter. In some embodiments, each ostomy-bag cover is enclosed in its own wrapper **345** made of, e.g., paper, cardboard, plastic, foil and/or the like.

The ostomy-bag cover **300** keeps water away from the ostomy bag (not shown) so that in some embodiments, the patient can shower or bathe without getting his or her ostomy bag wet. In some embodiments, the ostomy-bag cover is single-use, and is removed and disposed of after the patient bathes or showers.

In other embodiments of the present invention, only the outer protective layer **342** is removed prior to attaching the ostomy-bag cover to the abdominal skin of the patient. After showering or bathing, the patient removes the ostomy-bag cover and keeps it for a second use. For the second use of the ostomy-bag cover, the inner protective layer **341** is removed prior to attaching the ostomy-bag cover to the abdominal skin of the patient. The ostomy-bag is then removed and disposed of after the patient bathes or showers.

FIG. 3E is a top cross-sectional view of an ostomy-bag cover system **300**. In some embodiments, at least a first layer of protective material **343** and a second layer of protective material **344** cover the ostomy-bag-cover flange **311**. The proximal (patient-skin) side of the flange **311** is coated with an adhesive that releasably fastens the ostomy-bag cover to the abdominal skin of the patient **99**. The first layer of protective material **343** covers and protects the adhesive on the proximal (patient-skin) side of the flange **311**, and the proximal side first layer of protective material **343** is coated with an adhesive that releasably fastens the ostomy-bag cover to the abdominal skin of the patient **99**. The second layer of protective material **344** covers and protects the adhesive on proximal side of the first layer of protective material **343**. In use, the second protective layer **344** is removed, exposing the adhesive on the proximal side of the first protective layer **343**, and the ostomy-bag cover is attached to the abdominal skin of the patient. After showing or bathing, the ostomy-bag cover is removed for later reuse. For a second use, the first protective layer **343** is removed, exposing the adhesive on the proximal side of the flange **311**, and the ostomy-bag cover is attached to the abdominal skin of the patient. After the second use, the ostomy bag cover can be disposed of.

FIG. 3F is a back view and FIG. 3G is a top cross-sectional view of an ostomy-bag cover kit **301**. In some embodiments,

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the ostomy-bag cover kit includes an ostomy-bag cover body **360** and an adhesive-attachment band **350**, wherein the adhesive-attachment band is shaped substantially the same as the ostomy-bag-cover flange **311**. The adhesive-attachment band has a first surface which is coated with an adhesive and a second surface which is coated with an adhesive, and releasably fastens the ostomy-bag cover to the abdominal skin of the patient **99**. A first layer of protective material **351** covers and protects the adhesive on the first surface of the adhesive-attachment band and a second layer of protective material **352** covers and protects the adhesive on the second surface of the adhesive-attachment band. In some embodiments, each of the protective layers **351** and **352** is a single piece of material. In other embodiments, either or both of the protective layers are formed from more than one piece of material as shown in FIG. 3F. In some embodiments, the adhesive-attachment band **350** is constructed from a polymer film or polymer foam. In other embodiments, the adhesive-attachment band is constructed from paper. In some embodiments, the layers of protective material **351** and **352** can be paper. In other embodiments, the layers of protective material **351** and **352** can be plastic or other thin film.

In use, the patient removes the first layer of protective material **351** from the first surface of the adhesive-attachment band **350** and places the adhesive-attachment band on his or her abdomen in the appropriate location around the ostomy-bag flange. Then the patient removes the second protective layer **352** on the second side of the adhesive-attachment band and attaches the ostomy-bag-cover flange to the adhesive-attachment band forming watertight seal between the ostomy-bag cover and the patient's skin.

FIG. 4A is a front perspective view and FIG. 4B is a side perspective view of an ostomy-bag cover system **400**, according to some embodiments of the present invention. In some embodiments, wherein the ostomy-bag cover **400** includes a flange **411** and a water impermeable plastic bag cover **416**. The water impermeable plastic bag cover **416** is attached to the inner region **412** of the flange **411**, and the outer region **413** of the proximal surface of the flange **411** is covered with a pressure-sensitive adhesive that adheres to the skin of the abdomen of a patient **99** forming a water resistant seal between the patient and the ostomy-bag cover. The ostomy bag **80** is any of several commercially available ostomy bags and typically includes a stoma flange **81** and a stoma bag **82** attached to the stoma flange **81**, wherein a proximal surface of stoma flange **81** is covered with a pressure-sensitive adhesive that adheres to the abdomen of the patient **99**. In some embodiments, the ostomy-bag-cover flange **411** is sized so that there is uncovered patient skin **430** between the ostomy-bag-cover flange **411** and the ostomy-bag flange **81**. When an ostomy-bag cover is attached to a patient, the ostomy-bag cover and the adhesively formed seal result in a completely or nearly completely waterproof covering for the patient's ostomy bag. In some embodiments, the water impermeable plastic bag cover **416** includes a waterproof one-way vent **417** that allows air or other gases to be expelled from inside of the sealed ostomy-bag cover without the need to remove the ostomy-bag cover. This commonly referred to as "burping" the bag. In other embodiments, the water impermeable plastic bag cover **416** includes a watertight resealable opening **414**, through which the ostomy bag **80** can be emptied without removing the ostomy-bag cover. In some embodiments, the resealable opening is a zipper-style closure such as the type found on resealable ziplock plastic bags. In other embodiments, the opening is sealed with a clip or other fastener wherein the patient can unclip and unroll bottom of waterproof bag, pull out the ostomy bag from inside, empty the

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ostomy bag, and then roll water impermeable plastic bag cover and clip it to reestablish the watertight seal. In other embodiments, the opening is sealed with a Velcro® closure.

In some embodiments, the water impermeable material of plastic bag **416** is of sufficient strength and durability, such as a heavy gauge plastic, to permit the patient to swim with the ostomy-bag cover **400** in place, attached to the skin of his or her abdomen. This allows the patient to swim or engage in other wet activities without getting his or her ostomy bag wet.

In some embodiments, the ostomy bag cover **400** includes tabs **418** and **419** used to cover the navel of the patient **99** if the navel is an area near the outer region of the ostomy-bag-cover flange **413**. The appropriate tab is used depending of which side of the body the stoma is located, wherein the unneeded tab can be removed. Both tabs can be removed if neither is needed.

FIG. 5A is a front perspective view and FIG. 5B is a side perspective view of an ostomy-bag cover system **500** according to some embodiments of the present invention. The ostomy bag **80**, which is not part of the present invention, typically includes a stoma flange **81** with a stoma bag **84** attached to the stoma flange, and wherein a proximal surface of stoma flange **81** is covered with a pressure-sensitive adhesive that adheres to the skin of the abdomen of the patient **99**. The ostomy bag **80** is any of several commercially available ostomy bags.

The ostomy-bag cover **500** completely covers the ostomy bag **80**, wherein the ostomy-bag cover **500** includes a flange **511** that is attached to a flexible water resistant plastic film cover **516**, and wherein the ostomy-bag-cover flange **511** removeably attaches to the skin of the abdomen of the patient **99** with an adhesive on the proximal side of the flange **511** wherein the seal formed by the flange and the skin of the patient is substantially watertight. The ostomy-bag-cover flange **511** is sized in some embodiments to leave free space **530** between the ostomy-bag-cover flange **511** and the stoma flange **81**. Further, in other embodiments of the present invention, a tab **518** is attached to the ostomy-bag-cover flange **511** such that the tab **518** is used to cover and seal the perimeter of the area around the navel **98** of the patient **99** when the stoma is located near the navel such that ostomy-bag-cover flange **511** may not adequately seal all of the perimeter of the area around the ostomy bag **80** due to the uneven surface of the skin in the proximity of the navel. If not needed, the ostomy-bag-cover tab **518** can be removed, either by cutting it off, or in some embodiments, torn off along perforations at the connection of the tab and the ostomy-cover flange **511**. The ostomy-bag cover **500** keeps water away from the ostomy bag **80** so that in some embodiments, the patient can swim or engage in other water related activities, shower or bathe, without getting his or her ostomy bag wet. In some embodiments, the ostomy-bag cover is single-use, and is removed and disposed of after use.

In some embodiments, the flexible water resistant plastic film cover **516** includes a watertight, one-way, exhaust vent **517** through which any air or other gases inside of the sealed ostomy-bag cover can be removed without the need to requiring the patient to remove the ostomy-bag cover, commonly known as "burping" the cover. This makes the ostomy-bag cover less buoyant in water and improves the patient's experience of swimming or participating in other water related activities while wearing an ostomy bag and ostomy-bag cover. In other embodiments, the flexible water resistant plastic film cover **516** includes a resealable opening **514**, through which the ostomy bag **80** can be emptied without removing the ostomy-bag cover. When sealed, the resealable opening **514** is watertight so that the ostomy-bag cover provides a

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watertight cover for the ostomy bag. The resealable opening can be fastened shut using any one of a number of commercially available resealable closures including ziplock plastic bag zipper-style closures, Velcro® closures, and clips or other fasteners.

FIG. 6A is a front perspective view, and FIG. 6B is a side perspective view, of an ostomy-bag cover system 600, according to other embodiments of the present invention. An ostomy bag 80 is any of several commercially available ostomy bags, wherein the ostomy bag typically comprises a stoma bag 82 which collects patient 99 human waste emitted from the stoma, wherein the stoma bag 82 is attached to the stoma flange 81 and wherein the stoma flange 82 attaches to the abdomen of the patient 99 with an adhesive located on the proximal surface of the stoma flange 81. The ostomy-bag cover 600 includes a flange 611 and a liquid-impermeable flexible cover 616.

In some embodiments, the ostomy-bag-cover flange 611 includes an inner region 612 and an outer region 613, wherein the flange inner region 612 is attached to the liquid-impermeable flexible cover and the proximal (patient-skin) side of the ostomy-bag-cover flange 611 is coated with an adhesive that releasably fastens the ostomy-bag cover to the abdominal skin of the patient 99. The ostomy-bag cover when attached to the patient forms a substantially watertight covering over the ostomy bag 80. In some embodiments, the ostomy-bag-cover flange 611 is of a size that when attached to a patient, some free space (uncovered skin) 630 exists between the ostomy-bag-cover flange 611 and the stoma flange 81.

In some embodiments, the liquid-impermeable flexible cover 616 includes a watertight, one-way, exhaust vent 617 through which any air or other gases inside of the sealed ostomy-bag cover can be removed without the without requiring the patient to remove the ostomy-bag cover, commonly known as “burping” the cover. This makes the ostomy-bag cover less buoyant in water and improves the patient’s experience of swimming or participating in other water related activities while wearing an ostomy bag and ostomy-bag cover. In other embodiments, the liquid-impermeable flexible cover 616 includes a resealable opening 614, through which the ostomy bag 80 can be emptied without removing the ostomy-bag cover. When sealed, the resealable opening 614 is watertight so that the ostomy-bag cover provides a watertight cover for the ostomy bag. The resealable opening can be fastened shut using any one of a number of commercially available resealable closures including ziplock plastic bag zipper-style closures, Velcro® closures, and clips or other fasteners.

In some embodiments of the present invention, the adhesive coated side of the ostomy-bag-cover flange 611 is protected with at least one thin, easily removable layer of material during shipping to prevent the flange adhesive from adhering to anything prior to being attached to the patient’s skin. In some embodiments, the protective material can be paper. In other embodiments, the protective material can be plastic or other thin film. To attach the ostomy-bag cover, the patient first removes the protective layer from the inner region of the ostomy-bag-cover flange 612, and then positions the ostomy-bag cover in the desired location on his or her abdominal skin. The adhesive on the inner region of the flange holds the ostomy-bag cover to the patient’s skin and aids in the positioning of the ostomy-bag cover. Once the ostomy-bag cover is positioned as desired, the protective layer from the outer region of the flange 613 is removed and the flange is firmly pressed onto the patient’s skin, forming a watertight seal (in addition to any seal that may be provided by the inner region). In the process of attaching the ostomy-bag cover, the

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ostomy-bag cover may have to be repositioned one or more times, or may flex in handling, resulting in wrinkles in the flange and possibly areas on the flange where the adhesive has become weak. In such cases, the needed watertight seal between the flange and the skin of the patient may be compromised. The additional adhesive on the outer portion of the flange, which is not exposed until the ostomy-bag cover is positioned on the patient’s skin, ensures a good seal between the flange and the skin once the inner region is properly positioned and the release material has been removed from the outer region.

The ostomy-bag-cover flange can be produced in a variety of shapes, to better suit the needs of particular patients. FIG. 7 is a front perspective view of an ostomy-bag cover system 700, according to other embodiments of the present invention. An ostomy bag 80 is any of several commercially available ostomy bags, wherein the ostomy bag typically includes a stoma bag 82 which collects patient 99 human waste emitted from the stoma, wherein the stoma bag 82 is attached to the stoma flange 81 and wherein the stoma flange 81 attaches to the abdomen of the patient 99 with an adhesive located on the proximal surface of the stoma flange 81. The ostomy-bag cover 700 completely covers the ostomy bag 80, wherein the ostomy-bag cover 700 includes an ostomy-bag-cover flange 711 with an inner region 712 and an outer region 713. In some embodiments, the ostomy-bag-cover flange 711 is shaped as a square with rounded corners. The inner region of the flange 712 is attached to a flexible plastic film cover 716, and the ostomy-bag-cover flange 711 removeably attaches to the abdomen of the patient 99 with an adhesive on the proximal side of the flange 711, wherein the seal formed by the flange and the skin of the patient is substantially watertight. The ostomy-bag-cover flange 711 is sized in some embodiments to leave free space 730 between the ostomy-bag-cover flange 711 and the stoma flange 81. The ostomy-bag cover 700 keeps water away from the ostomy bag 80 so that in some embodiments, the patient can shower or bathe without getting his or her ostomy bag wet.

FIG. 8 is a front perspective view of an ostomy-bag cover system 800, according to other embodiments of the present invention. An ostomy bag 80 is any of several commercially available ostomy bags, wherein the ostomy bag typically includes a stoma bag 82 which collects patient 99 human waste emitted from the stoma, wherein the stoma bag 82 is attached to the stoma flange 81 and wherein the stoma flange 81 attaches to the abdomen of the patient 99 with an adhesive located on the proximal surface of the stoma flange 81. The ostomy-bag cover 800 completely covers the ostomy bag 80, wherein the ostomy-bag cover 800 includes an ostomy-bag-cover flange 811 with an inner region 812 and an outer region 813. In some embodiments, the ostomy-bag-cover flange 811 is shaped as a rectangle with rounded corners. The inner region of the flange 812 is attached to a flexible plastic film cover 816, and the ostomy-bag-cover flange 811 removeably attaches to the abdomen of the patient 99 with an adhesive on the proximal side of the flange 811, wherein the seal formed by the flange and the skin of the patient is substantially watertight. The ostomy-bag-cover flange 811 is sized in some embodiments to leave free space 830 between the ostomy-bag-cover flange 811 and the stoma flange 81. The ostomy-bag cover 800 keeps water away from the ostomy bag 80 so that in some embodiments, the patient can shower or bathe without getting his or her ostomy bag wet.

FIG. 9 is a front perspective view of an ostomy-bag cover system 900, according to other embodiments of the present invention. An ostomy bag 80 is any of several commercially available ostomy bags, wherein the ostomy bag typically

includes a stoma bag **82** which collects patient **99** human waste emitted from the stoma, wherein the stoma bag **82** is attached to the stoma flange **81** and wherein the stoma flange **81** attaches to the abdomen of the patient **99** with an adhesive located on the proximal surface of the stoma flange **81**. The ostomy-bag cover **900** completely covers the ostomy bag **80**, wherein the ostomy-bag cover **900** includes an ostomy-bag-cover flange **911** with an inner region **912** and an outer region **913**. In some embodiments, the ostomy-bag-cover flange **911** is shaped as an oval. The inner region of the flange **912** is attached to a flexible plastic film bag cover **916**, and the ostomy-bag-cover flange **911** removeably attaches to the abdomen of the patient **99** with an adhesive on the proximal side of the flange **911**, wherein the seal formed by the flange and the skin of the patient is substantially watertight. The ostomy-bag-cover flange **911** is sized in some embodiments to leave free space **930** between the ostomy-bag-cover flange **911** and the stoma flange **81**. The ostomy-bag cover **900** keeps water away from the ostomy bag **80** so that in some embodiments, the patient can shower or bathe without getting his or her ostomy bag wet.

As used herein, annulus shaped is shaped as the area between two circles in a plane.

As used herein, tubular shaped is shaped as a wall that is connected to itself, and can include the wall conforming to and surrounding a pyramid or conical frustum, the walls surrounding a cylinder, or the like.

In some embodiments, the present invention is an apparatus for covering an ostomy bag and its ostomy-bag-flange, the apparatus includes a bag formed from a polymer film that covers ostomy bag and its ostomy-bag-flange, the bag having a proximal end and a distal end. The apparatus further includes a cover flange having a distal side and a proximal side, wherein the distal side of the cover flange is connected to the top end of the bag forming a substantially waterproof seal between the cover flange and the top of the bag, wherein the proximal side of the cover flange is coated with an adhesive that releasably attaches the proximal side of the cover flange to a patient wearing an ostomy-bag-and-flange and forms a substantially waterproof seal between the flange and the skin of the patient, and wherein the flange contains an opening approximately centered in the flange that is large enough for the flange to surround the ostomy-bag-flange without contacting the ostomy-bag-flange. The cover bag and cover flange form a substantially waterproof cover over the ostomy-bag-and-flange.

As used wherein, a "type of polymer film" includes the chemical composition as well as the thickness, number of plies or sub-layers, texture, durometer, stiffness, opacity, adhesion quality and other characteristics of the film. The type of polymer film may also include any coatings such as metallic films, adhesives, release agents, anti-microbial agents, and the like. The type of polymer film may also include polymer foam material. Accordingly different types of polymer films may include different chemical compositions, but also include films having identical compositions but having different thicknesses, textures, durometers, stiffnesses, opacities, adhesion qualities, foam/solid (number or size of air pockets in the material) or other characteristics. In some embodiments, the polymer film is silicone. In some embodiments, the polymer film includes silicone. In some embodiments, the polymer film consists essentially of silicone.

In some embodiments, the cover bag or body of the present invention is coated with an anti-microbial agent or metal film. In some embodiments, the body is texturized or corrugated to provide enhanced expandability and stretchiness. In some

embodiments, the flange portion is formed as a thicker film and/or a film having more plies than the film of the body for improved durability and tear resistance. In some embodiments, the body of the cover is coated with a release agent in order to prevent it sticking to the adhesive of the flange, as well as allowing multiple covers to be stacked without sticking to one another, as well as facilitating unfolding of a single bag that has been folded for enhanced compact packaging. In some embodiments, the polymer film of the flange is made stiffer (e.g., in some embodiments, by making it thicker) than the film of the body to enhance handle-ability of the flange while maintaining flexibility and expandability of the cover's body. In some embodiments, the flange and/or body is made opaque or translucent for aesthetic reasons. In other embodiments, the flange is made transparent in order that the patient may visually inspect the seal to her or his skin. In some embodiments, the flange of the ostomy-bag cover is coated with one or more types of pressure-sensitive hypoallergenic adhesive, which in turn is covered a removable release film, also known as a backing, release liner or protective cover. (Note that the term "backing" is elsewhere occasionally used as the term for the release liner, but also elsewhere is often used as the term for the main non-sticky material of the tape rather than for the release liner. Thus, herein, the term release liner is used for the to-be-removed and -discarded portion.)

In some embodiments, the present invention is an ostomy-bag cover that includes a containment, or body, portion and an attachment, or flange, portion, constructed from a single piece of material. The body portion of the ostomy-bag cover encloses the patient's stoma bag and the stoma bag's attachment flange, and the flange portion of the ostomy-bag cover is adhesively attached to the patient's skin surrounding the flange of the stoma bag, forming a waterproof seal. The ostomy-bag cover, when attached to the patient in this manner, forms a waterproof covering over a patient's stoma bag, keeping the stoma bag and its flange dry while the patient showers, bathes, swims or participates in other water-related activities. In some embodiments, the material used to construct the cover and its flange is, or includes, a water-impermeable polymer, for example, the various compositions generally called silicone (e.g., polymerized siloxane or polysiloxane).

In some embodiments, the flange portion of the ostomy-bag cover has a constant thickness (see FIG. 10A) (or, in other embodiments, substantially constant or approximately constant thickness) (as shown in the inventor's co-pending U.S. patent application Ser. No. 13/018,210 titled "OSTOMY BAG WATERPROOF COVER AND METHOD," which is hereby incorporated herein by reference) and the flange portion is thicker than the body portion, in order to increase the strength and durability of the ostomy-bag cover where the cover attaches to the patient. In other embodiments, the flange portion of the ostomy-bag cover has a constant thickness (or, in other embodiments, substantially constant or approximately constant thickness), and is thinner than the body portion to increase the flexibility of the flange, allowing the flange to more readily conform to the patient's body and thereby form a better seal between the flange and the patient's skin. As used herein, "substantially constant" is defined to mean within plus or minus five percent (5%) of the average value. As used herein, "approximately constant" is defined to mean within plus or minus ten percent (10%) of the average value. For every embodiment described here that describes a thickness as constant, the present invention also encompasses embodiments having a substantially constant or approximately constant thickness.

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In FIGS. 10A-10J, the left-hand edge of the cover flange cross-sectional representation is the outer-circumference edge of the cover flange, while the right-hand edge shows a portion of the body of the ostomy-bag cover where it attaches to the cover flange.

In some embodiments, the flange portion is fabricated with a plurality of flange-material thicknesses (see FIG. 10B), including a thicker section where the flange portion connects or transitions to the body portion, in order to increase the durability and integrity of the ostomy-bag cover in the area of the flange-to-body transition, and a thinner section nearer the outer-most edge of the flange portion to increase the flexibility of the flange to improve the flange-to-skin seal. In other embodiments, the flange portion is fabricated with a plurality of thicknesses (see FIG. 10G), including a thinner ring-shaped (annular) section that extends most or all of the way around the circumference where the flange portion connects or transitions to the body portion, in order to increase the flexibility of the ostomy-bag cover in the area of the flange-to-body transition to improve the flange-to-skin seal, and a thicker section nearer the outer-most edge of the flange portion to increase the sturdiness of the flange to improve the removability of the flange from the patient, and the handling of the ostomy-bag cover in general. In various particular embodiments, the flange is fabricated to have one of a number of various intra-flange transition profiles (the shape of the flange cross-section between the thicker section of the flange and the thinner section of the flange), including, for example, a step, a ramp, or a taper (i.e., a tapered cross section meaning a continuous change of thickness from the body portion to the outer edge of the flange). In some embodiments, the flange portion of the ostomy-bag cover tapers continuously from the thicker section of the flange to the thinner section of the flange (see FIG. 10F). In other embodiments, the invention uses a step transition from the thicker section of the flange to the thinner section of the flange (see FIG. 10B). In yet other embodiments, there is a ramp transition from the thicker section of the flange to the thinner section of the flange (see FIG. 10C, FIG. 10D and FIG. 10E). In some embodiments, the ramp width (the length of the ramp along a radius of the flange) is about 10% of the width of the flange. In other embodiments, the ramp width is between about 10% and about 30% of the width of the flange. In other embodiments, the ramp width is between about 20% and about 40% of the width of the flange. In other embodiments, the ramp width is between about 30% and about 50% of the width of the flange. In other embodiments, the ramp width is between about 10% and about 50% of the width of the flange.

In some embodiments, the flange portion of the ostomy-bag cover extends inside the diameter of where the body portion connects to the flange portion of the ostomy-bag cover (see FIG. 10H, FIG. 10I and FIG. 10J) (e.g., in some embodiments, the body portion connects to the flange along a closed-curve line between the inner diameter and the outer diameter of the flange).

In some embodiments, the radial width of the thicker section of the flange is approximately the same as the radial width of the thinner section of the flange (i.e., the radial width of each is about 50% of the total radial width for more than 65% of the circumference of the flange). In some embodiments, the flange portion of the ostomy-bag cover has a total radial width of about one inch (about 25.4 mm). In other embodiments, the radial width of the thicker section of the flange is between about 1% and 25% of the total radial width of the flange for at least about 65% of the circumference of the flange. In other embodiments, the radial width of the thicker section of the flange is between about 25% of the total radial

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width of the flange and about 75% of the total radial width of the flange for at least about 65% of the circumference of the flange. In other embodiments, the thicker section of the flange includes between about 55% and 75% of the circumference of the flange. In other embodiments, the thicker section of the flange includes between about 65% and 85% of the circumference of the flange. In other embodiments, the thicker section of the flange includes between about 75% and 95% of the circumference of the flange. In other embodiments, the thicker section of the flange includes the entire circumference of the flange.

In some embodiments, the flange portion of the ostomy-bag cover has a total radial width of about one-half inch (about 13 mm). In other embodiments, the flange portion has a total radial width of between about 0.25 inch (about 6 mm) and about 0.75 inch (about 19 mm). In other embodiments, the flange portion has a total radial width of between about 0.5 inch (about 13 mm) and about one inch (about 25.4 mm). In other embodiments, the flange portion has a total radial width of between about 0.75 inch (about 19 mm) and about 1.25 inch (about 32 mm). In other embodiments, the flange portion has a total radial width of between about 0.5 inch (about 13 mm) and about 1.25 inch (about 32 mm).

In some embodiments, the ostomy-bag cover is produced in multiple sizes, with the smallest sizes being suitable for use with infants, somewhat larger sizes suitable for use with children, still larger sizes suitable for use with small body-size adults, and large sizes suitable for use with large body-sized adults. In some embodiments, the body portion of the ostomy bag cover has a diameter of about six inches (about 152 mm). In other embodiments, the body portion of the ostomy bag cover has a diameter of between about five inches and seven inches (between about 127 mm and about 178 mm). In some embodiments, the body portion of the ostomy bag cover has a diameter of about two inches (about 51 mm), for use by very small children. In other embodiments, the body portion of the ostomy bag cover has a diameter of between about two inches and four inches (between about 51 mm and 102 mm). In other embodiments, the body portion of the ostomy bag cover has a diameter of between about three inches and five inches (between about 76 mm and 127 mm). In other embodiments, the body portion of the ostomy bag cover has a diameter of between about four inches and six inches (between about 102 mm and 152 mm). In other embodiments, the body portion of the ostomy bag cover has a diameter of between about six inches and eight inches (between about 152 mm and 203 mm). In other embodiments, the body portion of the ostomy bag cover has a diameter of between about seven inches and nine inches (between about 178 mm and 229 mm).

In some embodiments of the present invention as shown in FIG. 17, the flange portion 1710 of the ostomy-bag cover is attached to patient with a pressure-sensitive releasable adhesive 1720. In some embodiments, an adhesive tape is attached to the patient-skin-contact side of the flange. The adhesive tape includes a backing 1722 (i.e., the tape substrate or fabric) that has a front side and a back side, and that is coated on the front side with an adhesive that releasably adheres to the patient's skin. In some embodiments, the adhesive is a pressure-sensitive adhesive. In some embodiments, the adhesive is hypoallergenic. In some embodiments, the adhesive on the front side of the tape backing is covered by a release liner 1724, also known as a release film, which protects the adhesive during shipping, distribution and other handling of the ostomy-bag cover prior to use. At the time of application (that is, at the time of attaching an ostomy bag cover to a patient's skin), the release liner is removed to expose the adhesive. The

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back side of the tape backing is attached to the flange of the ostomy-bag cover. In some embodiments, the adhesive tape is pre-attached to the flange using an appropriate adhesive (i.e., one that readily adheres the material of the tape backing to the material of the flange) applied to the flange and/or the back side of the tape backing.

In other embodiments, the adhesive tape 1720 is a double-sided (also known as double-stick) tape, with adhesive on both the front and the back sides of the backing. The adhesive on the back side of the tape backing is configured to adhere to the material of the flange, and attaches the tape to the flange. In some embodiments, the adhesive on the back side of the tape backing is releasable, and the double-sided tape is removed from the flange portion of the ostomy-bag cover after each use of the ostomy-bag cover. A new piece of double-sided tape is then attached to the flange for a subsequent use of the ostomy-bag cover, making the ostomy-bag cover reusable. In some embodiments, a reattachment layer of material 1730 is permanently affixed to the patient-skin-contact side of the flange portion of the ostomy bag cover. The reattachment layer of material on the flange facilitates the application and removal of double-sided adhesive tape to the flange by providing a surface and material that more readily adheres to the adhesive on the back side of the tape than the material of the flange and allows for easy removal of the double-sided tape. In some embodiments, the reattachment layer material is or includes a non-silicone polymer or other thin film. In other embodiments, the reattachment layer material is or includes paper.

In some embodiments of the present invention, the back side of the adhesive tape backing is heat welded to the flange portion of the ostomy-bag cover. In other embodiments, the back side of the adhesive tape backing is solvent welded to the flange portion of the ostomy-bag cover. In other embodiments, the back side of the adhesive tape backing is attached to the flange portion of the ostomy-bag cover with a spray-on adhesive applied to the back side of the adhesive tape backing and/or the patient-skin-contact side of the flange portion of the ostomy bag cover.

In some embodiments, the flange and body portions of the ostomy-bag cover are formed as a single piece of silicone material. A silicone-compatible adhesive is applied to the patient-skin side of the flange, and a preformed, annular-shaped piece of tape (one having a pressure-sensitive adhesive on a front face and a surface on the back face that adheres to the silicone-compatible adhesive on the flange of the ostomy-bag cover) is attached to the flange such that the back face of the tape is fixed to the flange. In some embodiments, pressure and/or heat are applied to the tape and flange to securely fix the tape to the flange.

In some embodiments, the body portion of the ostomy-bag cover is shaped to resemble a truncated cone (i.e., having a substantially circular base) as shown in FIGS. 11A and 11B, and in FIG. 12A and FIG. 12B. In other embodiments, the body portion is shaped like a truncated elliptical cone (i.e., having a substantially elliptical base) as shown in FIGS. 13A and 13B. In other embodiments, the body portion is shaped like a truncated rounded-rectangle pyramid (i.e., a truncated pyramid having a substantially rounded-rectangle base). In other embodiments, the body portion is substantially shaped like a spherical cap or dome as shown in FIGS. 14A and 14B. In other embodiments, the body portion is shaped to resemble a spherical segment as shown in FIG. 16A and FIG. 16B. In other embodiments, the body portion is shaped like an ellipsoid segment as shown in FIG. 15A and FIG. 15B. The list of exemplary embodiments provides some example shapes and is not intended to preclude use of other suitable shapes.

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In some various embodiments, the ostomy-bag cover is fabricated to have any selected one of the number of various flange-portion profiles described herein combined with any selected one of the number of various body-portion shapes described herein. In other embodiments, other suitable flange-portion profiles and body-portion shapes are used.

In some embodiments, the present invention is suitable for use as a temporary waterproof covering for other medical situations. A suitably sized and shaped ostomy-bag cover built according to the present invention can be used to cover an intravenous-connection site or wound dressing on a patient while the patient is bathing, showering or otherwise exposed to water.

In some embodiments, a plurality of ostomy-bag covers are provided wherein each ostomy-bag cover is enclosed in its own wrapper made of, e.g., paper, cardboard, plastic, foil and/or the like. In some embodiments, the wrapper is imprinted with a decorative design to promote the brand name and/or to disguise the contents.

In some embodiments, the present invention includes a resealable opening at the bottom of the bag wherein the opening the patient to remove excess air in the bag covering the ostomy-bag-and-flange, and wherein the opening can be sealed to prevent water from entering the bag. In other embodiments, the resealable opening at the bottom of the bag can be used to empty the ostomy bag without removing the bag and its attached flange.

In some embodiments, the cover flange is shaped substantially like an annulus. In other embodiments, the cover flange can be shaped as a square or rectangle with rounded corners. In other embodiments, the cover flange can be shaped as an oval.

In other embodiments, the bag and attached cover flange form a single-use, substantially waterproof cover over the ostomy-bag-and-flange for use in a shower wherein the patient can shower without the need to dry the ostomy bag and its ostomy-bag flange, or to remove the ostomy bag during the shower.

In other embodiments, the present invention provides a bag formed from a flexible waterproof material, the bag having a top end and a bottom end, and fashioned to cover an ostomy-bag-and-flange. The present invention further provides a flange having a distal side and a proximal side, wherein the distal side of the flange is connected to the top end of the bag forming a substantially waterproof seal between the flange and the top of the bag, wherein the proximal side is coated with an adhesive that releasably attaches the proximal side of the flange to a patient wearing an ostomy-bag-and-flange and forms a substantially waterproof seal between the flange and the skin of a patient, and wherein the flange contains an opening approximately centered in the flange that is large enough for the flange to surround the ostomy-bag-flange without contacting the ostomy-bag-flange. A resealable opening is provided at the bottom of the bag wherein the opening allows a patient to remove excess air in the bag covering the ostomy-bag-and-flange, and wherein the opening can be sealed to prevent water from entering the bag. The bag and flange form a substantially waterproof cover over the ostomy-bag-and-flange.

In some embodiments, the present invention is an apparatus for protectively covering an ostomy bag of a patient, wherein the ostomy bag has an ostomy-bag flange, and the ostomy-bag flange adheres to the patient's skin surrounding a stoma. The present invention includes an ostomy-bag cover having a cover-side portion formed from a polymer film, the cover-side portion having a tubular body, a proximal end opening and a distal end opening, wherein the ostomy-bag

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cover covers the ostomy bag and its ostomy-bag flange in order to inhibit water from reaching the ostomy bag and its ostomy-bag flange. In some embodiments, the present invention further includes a cover-flange portion connected to the cover-side portion and surrounding the proximal end opening, the cover-flange portion having a patient-skin-contact side and a distal side, wherein the patient-skin-contact side has a pressure-sensitive adhesive that releasably attaches the proximal side of the flange to the patient's skin surrounding the ostomy-bag flange and forms a water-resistant seal to the patient's skin, and wherein the cover-flange portion contains an opening that is large enough for the cover-flange portion to surround the ostomy-bag-flange without contacting the ostomy-bag-flange. The present invention further includes a resealable vent at the distal end of the cover-side portion, wherein the vent facilitates removal of excess air within the ostomy-bag cover surrounding the ostomy bag and its ostomy-bag flange, wherein the vent is sealable to prevent water from entering the ostomy-bag cover, and whereby the ostomy-bag cover forms a water-resistant cover over the ostomy bag and its ostomy-bag flange.

In some embodiments, the present invention provides an apparatus kit for covering an ostomy bag of a patient, the ostomy bag having an ostomy-bag flange, wherein the ostomy-bag flange adheres to the patient's skin surrounding a stoma. The apparatus kit includes an ostomy-bag-cover body, wherein the ostomy-bag-cover body includes: a protective covering formed from a liquid-impermeable membrane, wherein the protective covering is substantially flat before use, and wherein the protective covering unfolds to fit over the ostomy bag and its ostomy-bag flange and a cover-flange portion connected to the protective covering, the cover-flange portion having a patient-skin-contact side and a distal side. The kit further includes an adhesive-attachment band, the adhesive-attachment band having a first surface with a pressure-sensitive adhesive, and a second surface with a pressure-sensitive adhesive, wherein the adhesive-attachment band is shaped approximately the same as the cover-flange, wherein the pressure-sensitive adhesive of the first side of the adhesive-attachment band is covered by a first removable piece of release film, and the pressure-sensitive adhesive of the second side of the adhesive-attachment band is covered by a second removable piece of release film, wherein the adhesive-attachment band releasably attaches to an area of the patient's skin surrounding the ostomy-bag flange and to the patient-skin-contact side of the cover-flange in order to form a watertight seal to an area of the patient's skin that surrounds the ostomy-bag-flange.

In some embodiments, the adhesive-attachment band includes a polymer film having the pressure-sensitive adhesive on both of two major faces of the film.

In some embodiments, the adhesive-attachment band is constructed, at least in part, of paper.

In some embodiments, the present invention provides an apparatus for covering an ostomy bag of a patient, the ostomy bag having an ostomy-bag flange, wherein the ostomy-bag flange is configured to adhere to the patient's skin surrounding a stoma. This apparatus includes an ostomy-bag cover, wherein the ostomy-bag cover is configured to cover the ostomy bag and its ostomy-bag flange in order to prevent water from reaching the ostomy bag and its ostomy-bag flange, and wherein the ostomy-bag cover includes: a body formed from a liquid-impermeable membrane; and a cover flange connected to the body, the cover flange having a patient-skin-contact face and a distal face, wherein the patient-skin-contact face has a pressure-sensitive adhesive that releasably attaches the patient-skin-contact face of the

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flange to the patient's skin surrounding the ostomy-bag flange and forms a watertight seal to an area of the patient's skin that surrounds the ostomy-bag-flange.

In some embodiments, the cover flange has a plurality of areas each having a different material thickness, including a first area adjacent to the body and a second area adjacent to the first area and nearer an outer-most edge of the cover flange, wherein the material thickness of second area is thinner than the material thickness of the first area.

In some embodiments, the ostomy-bag cover body has a truncated-circular-cone shape.

In some embodiments, the ostomy-bag cover body has a truncated-elliptical-cone shape.

In some embodiments, the pressure-sensitive adhesive on the patient-skin-contact side of the flange is provided by adhesive tape which is attached to the flange with an adhesive.

In some embodiments, the cover-flange portion is constructed of a first type of polymer film, wherein the ostomy-bag cover's body is constructed of a second type of polymer film different than the first type of polymer film, and wherein the polymer film of the flange is fused to the polymer film of the body.

In some embodiments, the liquid-impermeable membrane forming the body and the adhesive on the cover-flange portion are configured to stay intact and in place when the patient swims while wearing the ostomy-bag cover.

In some embodiments, the cover flange includes at least a first flap extension of the cover flange, and a second flap extension of the cover flange at a non-zero distance along a circumference of the cover flange from the first flap extension.

In some embodiments, the ostomy-bag cover further includes a removable peel-away covering over the adhesive on the flange, and wherein the ostomy-bag cover is enclosed within a removable disposable wrapper.

In some embodiments, the adhesive on the cover-flange portion is hypoallergenic.

In some embodiments, an outer edge of the cover flange is substantially rectangular with rounded corners.

In some embodiments, the pressure-sensitive adhesive of the cover flange has a first annular region covered by at least one first removable piece of release film, and a second annular region that is concentric to the first annular region and covered by at least one second removable piece of release film.

In some embodiments, the present invention provides a method for making an ostomy-bag cover for use over an ostomy bag of a patient, the ostomy bag having an ostomy-bag flange, wherein the ostomy-bag flange adheres to the patient's skin surrounding a stoma, wherein the ostomy-bag cover covers the ostomy bag and its ostomy-bag flange in order to restrict water from reaching the ostomy bag and its ostomy-bag flange. This method includes fabricating a liquid-impermeable-membrane body of the ostomy-bag cover and a cover flange connected to the body, wherein the body is configured to cover the ostomy bag and its ostomy-bag flange in order to prevent water from reaching the ostomy bag and its ostomy-bag flange, and wherein the cover flange has a proximal face that faces the patient and an opposite distal face, providing a preformed adhesive tape ring, wherein the adhesive tape ring has a back face and a front face and wherein the front face of the adhesive tape ring has a pressure-sensitive adhesive; applying adhesive to the proximal face of the cover flange; and attaching the adhesive tape ring to the flange, wherein the adhesive fixes the back side of the adhesive tape ring to the proximal side of the flange such that a first annular region of the proximal side of the cover flange of the ostomy-bag cover adheres to the patient with the pressure-sensitive

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adhesive and forms a watertight seal to the patient's skin, and such that, when in use, the ostomy-bag cover forms a substantially waterproof cover over the ostomy bag and its ostomy-bag flange.

Some embodiments of the method further include fabricating the cover flange to have a plurality of areas each having a different material thickness, including a first area adjacent to the body and a second area adjacent the first area and nearer an outer-most edge of the cover flange, wherein the material thickness of second area is thinner than the material thickness of the first area.

In some embodiments, the liquid-impermeable membrane includes a polymer film.

Some embodiments of the method further include fabricating the cover flange with a plurality of material thicknesses, wherein the cover flange's thickness tapers from a thicker section adjacent to the body to a thinner section nearer an outer-most edge of the cover flange.

Some embodiments of the method further include forming a second adhesive annular region, concentric to, and outside of, the first annular region of the cover-flange portion of the ostomy-bag cover, with the pressure-sensitive adhesive thus providing for an additional watertight seal between the ostomy-bag cover and the patient's skin.

Some embodiments of the method further include providing a first removable peel-away covering over the adhesive on the first annular region of the cover flange; providing a second removable peel-away covering over the adhesive on a second annular region of the cover flange that is concentric to, and outside of, the first annular region of the cover flange; and adhering the second annular region of the proximal side of the cover-flange portion of the ostomy-bag cover to the patient after adhering the first annular region to the patient.

In some embodiments, the present invention provides an apparatus for covering an ostomy bag of a patient, the ostomy bag having an ostomy-bag flange, wherein the ostomy-bag flange adheres to the patient's skin surrounding a stoma. This apparatus includes protective film means (as described and shown herein) for covering the ostomy bag and its ostomy-bag flange in order to prevent water from reaching the ostomy bag and its ostomy-bag flange; and pressure-sensitive adhesive flange means (as described and shown herein) for attaching the protective film means to a patient, wherein the flange means for attaching is connected to the means for covering, wherein the flange means for attaching has a plurality of areas each having a different thickness, including a first annular area that is adjacent the means for covering and that has a width about half of a total width of the cover flange and having a first thickness, and a second annular area that is adjacent the first annular area and that has a width about half of a total width of the cover flange and having a second thickness that is thinner than the first thickness. Some embodiments of the apparatus further include means for extending the water-resistant seal of the flange to further cover the patient's umbilicus. Some embodiments of the apparatus further include removable means for protecting the means for attaching. Some embodiments of the apparatus further include first removable means for protecting an adhesive coating on a first annular region of the means for attaching to allow the ostomy-bag cover to be positioned and adhered to the patient's skin; and second removable means for protecting an adhesive coating on a second annular region surrounding the first annular region to allow the ostomy-bag cover to be better sealed to the patient's skin after the ostomy-bag cover is positioned.

In some embodiments, the present invention provides an apparatus for covering an ostomy bag of a patient, the ostomy

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bag having an ostomy-bag flange, wherein the ostomy-bag flange adheres to the patient's skin surrounding a stoma. This apparatus includes a protective covering formed from a liquid-impermeable membrane, wherein the protective covering is substantially flat before use, and wherein the protective covering unfolds to fit over the ostomy bag and its ostomy-bag flange; and a cover-flange portion connected to the protective covering, the cover-flange portion having a patient-skin-contact side and a distal side, wherein the patient-skin-contact side includes a pressure-sensitive adhesive that releasably attaches the patient-skin-contact side of the cover-flange to an area of the patient's skin surrounding the ostomy-bag flange and forms a watertight seal to an area of the patient's skin that surrounds the ostomy-bag-flange. In some embodiments, the cover-flange portion includes at least a first flap extension to cover at least the umbilicus of the patient. In some embodiments, the ostomy-bag cover forms a single-use, disposable, substantially waterproof cover over the ostomy bag and its ostomy-bag flange. In some embodiments, the cover-flange portion is constructed of a first type of polymer film, wherein the body is constructed of a second type of polymer film different than the first type of polymer film, and wherein the polymer film of the flange is fused to the polymer film of the body.

In some embodiments, the present invention provides an apparatus kit for covering an ostomy bag of a patient, the ostomy bag having an ostomy-bag flange, wherein the ostomy-bag flange adheres to the patient's skin surrounding a stoma. This apparatus kit includes an ostomy-bag-cover body, wherein the ostomy-bag-cover body includes: a protective covering formed from a liquid-impermeable membrane, wherein the protective covering is substantially flat before use, and wherein the protective covering unfolds to fit over the ostomy bag and its ostomy-bag flange, and a cover-flange portion connected to the protective covering, the cover-flange portion having a patient-skin-contact side and a distal side; and an adhesive-attachment band, the adhesive-attachment band having a first surface with a pressure-sensitive adhesive, and a second surface with a pressure-sensitive adhesive, wherein the adhesive-attachment band is shaped approximately the same as the cover-flange, wherein the pressure-sensitive adhesive of the first side of the adhesive-attachment band is covered by a first removable piece of release film, and the pressure-sensitive adhesive of the second side of the adhesive-attachment band is covered by a second removable piece of release film, wherein the adhesive-attachment band releasably attaches to an area of the patient's skin surrounding the ostomy-bag flange and to the patient-skin-contact side of the cover-flange in order to form a watertight seal to an area of the patient's skin that surrounds the ostomy-bag-flange. In some embodiments, the adhesive-attachment band includes a polymer film having the pressure-sensitive adhesive on both of two major faces of the film. In some embodiments, the adhesive-attachment band is made of a material that includes paper.

It is to be understood that the above description is intended to be illustrative, and not restrictive. Although numerous characteristics and advantages of various embodiments as described herein have been set forth in the foregoing description, together with details of the structure and function of various embodiments, many other embodiments and changes to details will be apparent to those of skill in the art upon reviewing the above description. The scope of the invention should be, therefore, determined with reference to the appended claims, along with the full scope of equivalents to which such claims are entitled. In the appended claims, the terms "including" and "in which" are used as the plain-En-

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glish equivalents of the respective terms “comprising” and “wherein,” respectively. Moreover, the terms “first,” “second,” and “third,” etc., are used merely as labels, and are not intended to impose numerical requirements on their objects.

What is claimed is:

1. An apparatus for covering an ostomy bag of a patient, the ostomy bag having an ostomy-bag flange, wherein the ostomy-bag flange adheres to the patient’s skin surrounding a stoma, the apparatus comprising:

protective film means for covering the ostomy bag and its ostomy-bag flange in order to prevent water from reaching the ostomy bag and its ostomy-bag flange; and

pressure-sensitive adhesive flange means for attaching the protective film means to a patient, wherein the flange means for attaching is connected to the means for covering, wherein the flange means for attaching has a plurality of areas each having a different thickness, including a first annular area that is adjacent the means for covering and that has a width about half of a total width of the cover flange and having a first thickness, and a second annular area that is adjacent the first annular area and that has a width about half of a total width of the cover flange and having a second thickness that is thinner than the first thickness,

wherein the pressure-sensitive flange means for attaching forms a water-resistant seal to an area of the patient’s skin, the apparatus further comprising means for extending the water-resistant seal to further cover the patient’s umbilicus.

2. The apparatus of claim 1, wherein the flange means for attaching has a thickness that tapers from the first thickness adjacent to the body to the second thickness nearer an outer-most edge of the cover flange.

3. The apparatus of claim 1, wherein the flange means for attaching has a plurality of pressure-sensitive adhesive annular regions including a first adhesive annular region and a separate second adhesive annular region, concentric to, and outside of, the first adhesive annular region of the flange means for attaching, wherein the plurality of pressure-sensitive adhesive annular regions provide an additional watertight seal between the ostomy-bag cover and the patient’s skin.

4. The apparatus of claim 3, wherein the flange means for attaching includes:

a first removable peel-away covering over the adhesive on the first adhesive annular region of the flange means for attaching;

a second removable peel-away covering over the adhesive on the second adhesive annular region of the flange means for attaching that is concentric to, separate from, and outside of, the first adhesive annular region of the flange means for attaching.

5. An apparatus for covering an ostomy bag of a patient, the ostomy bag having an ostomy-bag flange, wherein the ostomy-bag flange is configured to adhere to the patient’s skin surrounding a stoma, the apparatus comprising:

an ostomy-bag cover, wherein the ostomy-bag cover is configured to cover the ostomy bag and its ostomy-bag flange in order to prevent water from reaching the ostomy bag and its ostomy-bag flange, and wherein the ostomy-bag cover includes:

a body formed from a liquid-impermeable membrane; and a cover flange connected to the body, the cover flange having a patient-skin-contact face and a distal face, wherein the patient-skin-contact face has a pressure-sensitive adhesive that releasably attaches the patient-skin-contact face of the flange to the patient’s skin surrounding the ostomy-bag flange and forms a watertight

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seal to an area of the patient’s skin that surrounds the ostomy-bag-flange, wherein the watertight seal formed by the cover flange is configured such that the patient’s umbilicus is contained within a perimeter formed by the watertight seal.

6. The apparatus of claim 5, wherein the cover flange has a plurality of areas each having a different material thickness, including a first area adjacent to the body and a second area adjacent the first area and nearer an outer-most edge of the cover flange, wherein the material thickness of second area is thinner than the material thickness of the first area.

7. The apparatus of claim 5, wherein the ostomy-bag cover body has a truncated-circular-cone shape.

8. The apparatus of claim 5, wherein the ostomy-bag cover body has a truncated-elliptical-cone shape.

9. The apparatus of claim 5, wherein the pressure-sensitive adhesive on the patient-skin-contact side of the flange is provided by adhesive tape which is attached to the flange with an adhesive.

10. The apparatus of claim 5, wherein the cover flange includes at least a first flap extension of the cover flange, and a second flap extension of the cover flange at a non-zero distance along a circumference of the cover flange from the first flap extension.

11. The apparatus of claim 5, wherein an outer edge of the cover flange is substantially rectangular with rounded corners.

12. The apparatus of claim 5, wherein the pressure sensitive adhesive includes an adhesive tape ring, wherein the adhesive tape ring has a back face and a front face and wherein the front face of the adhesive tape ring has the pressure-sensitive adhesive and the back face is attached to the patient-skin-contact face of the flange with an adhesive.

13. The apparatus of claim 5, wherein the cover flange has a plurality of material thicknesses, wherein the cover flange’s thickness tapers from a thicker section adjacent to the body to a thinner section nearer an outer-most edge of the cover flange.

14. The apparatus of claim 5, wherein the pressure-sensitive adhesive on the patient-skin-contact face of the cover flange includes a first adhesive region, and a second adhesive region that is concentric to, and outside of, the first adhesive region.

15. An apparatus for covering a medical dressing on a patient, the apparatus comprising:

a cover, wherein the cover is configured to cover the medical dressing in order to prevent water from reaching the medical dressing, and wherein the cover includes:

a body formed from a liquid-impermeable membrane; and

a cover flange connected to the body, the cover flange having a patient-skin-contact face and a distal face, wherein the patient-skin-contact face has a pressure-sensitive adhesive that releasably attaches the patient-skin-contact face of the flange to the patient’s skin surrounding the medical dressing and forms a watertight seal to an area of the patient’s skin that surrounds the medical dressing, wherein the cover flange has a first thickness in a first annular area next to the body and a second constant thickness in a second annular area surrounding the first annular area that is thinner than the first thickness.

16. The apparatus of claim 15, wherein the medical dressing further includes an intravenous-connection site.

17. An apparatus for covering a medical dressing on a patient, the apparatus comprising:

a cover, wherein the cover is configured to cover the medical dressing in order to prevent water from reaching the medical dressing, and wherein the cover includes:
a body formed from a liquid-impermeable membrane; and
a cover flange connected to the body, the cover flange 5
having a patient-skin-contact face and a distal face,
wherein the patient-skin-contact face has a pressure-sensitive adhesive that releasably attaches the patient-skin-contact face of the flange to the patient's skin surrounding the medical dressing and forms a watertight 10
seal to an area of the patient's skin that surrounds the medical dressing, wherein the cover flange has a first thickness in a first annular area next to the body, a tapered thickness in a second annular region surrounding the first annular area, and a third constant thickness 15
in a third annular area, surrounding the second annular area, that is thinner than the first thickness of the first annular area.

18. The apparatus of claim **15**, wherein an outer edge of the cover flange is substantially rectangular with rounded corners. 20

19. The apparatus of claim **15**, wherein an outer edge of the cover flange is oval shaped.

20. The apparatus of claim **17**, wherein an outer edge of the cover flange is substantially rectangular with rounded corners. 25

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